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In The

Supreme Court of the United States

October Term, 1994

NOVOPHARM, INC., and NOVOPHARM LTD.,

Petitioners,

v.

BURROUGHS WELLCOME CO.,

Respondent.

Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

PETITION FOR A WRIT OF CERTIORARI

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78 pp

QUESTIONS PRESENTED

Whether the Court of Appeals for the Federal Circuit, in affirming a judgment entered under Rule 50(a), *Fed.R.Civ.P.*, improperly usurped the role of the jury by accepting evidence that was presented to the jury by one party, while ignoring evidence to the contrary that was presented in an offer of proof by the other party.

Whether one who exercises skill beyond that of a "pair of hands" to reduce to practice an invention, when others of ordinary skill in the art have failed, is an inventor.

PARTIES TO PROCEEDING

In addition to the parties identified in the caption to the case, Barr Laboratories, Inc. was a party to the proceeding below and Wellcome, Plc. is the parent corporation of the party Burroughs Wellcome Co.

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PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Petitioners Novopharm Ltd. and Novopharm, Inc. (hereinafter "Novopharm") respectfully petition for a writ of certiorari to review the decision of the United States Court of Appeals for the Federal Circuit, entered in the above-entitled proceedings on November 22, 1994.

OPINION BELOW

The opinion of the Court of Appeals for the Federal Circuit is reported at 40 F.3d 1223 and reproduced in the Appendix ("App.") at pp. 1a-28a. The opinion and order of the district court, entered July 22, 1993, is reported at 828 F.Supp. 1208 and reproduced in the App. at pp. 29a-44a.

JURISDICTION

The judgment of the Court of Appeals for the Federal Circuit was entered on November 22, 1994. Novopharm filed a petition for rehearing, which was denied on December 15, 1994. App. at p. 45a. This Court has jurisdiction to review the judgment of the Court of Appeals pursuant to 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS AND RULES INVOLVED

35 U.S.C. § 116 provides in pertinent part:

> When an invention is made by two or more persons jointly, they shall apply for patent jointly and each make the required oath, except as otherwise provided in this title. Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent.

Rule 50(a) of the Federal Rules of Civil Procedure provides in pertinent part:

> If during a trial by jury a party has been fully heard on an issue and there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue, the court may determine the issue against that party and may grant a motion for judgment as a matter of law against that party with respect to a claim or defense that cannot under the controlling law be maintained or defeated without a favorable finding on that issue.

STATEMENT OF THE CASE

This case is one of alleged patent infringement which was being tried before a jury. Jurisdiction arose under 28 U.S.C. § 1338(a). Burroughs Wellcome Co. ("BW") charged Novopharm with patent infringement under 35 U.S.C. § 271(e) based on Novopharm Ltd.'s filing of an Abbreviated New Drug Application ("ANDA") with the

Food and Drug Administration for the manufacture and sale of zidovudine ("AZT") capsules. BW charged Novopharm with infringement of U.S. Patent Nos. 4,724,232; 4,828,838; 4,833,130; 4,837,208; 4,818,538; and 4,818,750. These six patents relate to the use of AZT as an effective treatment against HIV/AIDS in humans, and to certain physiological effects of such use.

Novopharm's central defense at trial was that the patents are invalid under 35 U.S.C. § 116 because of a non-joinder of inventors in that BW, with deceptive intent, had failed to join researchers at the National Institutes of Health ("NIH") – Dr. Samuel Broder, Dr. Hiroaki Mitsuya, and Dr. Robert Yarchoan – as coinventors. Novopharm further contended that all the patents in suit are unenforceable because of BW's inequitable conduct in purposefully not joining any of the NIH researchers as coinventors of the patents.

Trial began on June 28, 1993, with the presentation of evidence by BW. The issue of admissibility of certain evidence *vis-a-vis* the district court's legal definition of inventorship was repeatedly raised by all sides. On the morning of July 20, 1993, during the cross-examination by Barr's counsel of the fifth of BW's nearly ninety identified witnesses, the Court's sustained objection as to the admissibility of one of Barr's exhibits started an avalanche which resulted in the entry of judgment against Novopharm pursuant to Rule 50.

At that point, the trial was abruptly recessed. Within hours the district court delivered a "draft" Order to counsel which reflected certain "findings" of fact and the identification of Rule 50, *Fed.R.Civ.P.*, as the procedural

vehicle the court had chosen to end the case. Following a brief discussion shortly thereafter, the district court gave Novopharm until 9:00 a.m. the next morning to consider the draft Order and to prepare an offer of proof.

When the court reconvened the following morning, Novopharm submitted an offer of proof pursuant to Rule 103, *Fed.R.Evid.* Counsel for Novopharm also objected to the Rule 50 procedure and stated that, in contradiction of the draft Order, there remained triable issues, stating, "That's why we have a jury trial." Upon inquiry, counsel for Novopharm asserted that Novopharm had not been fully heard. In the face of that objection, the district court directed that Novopharm could have until 8:30 a.m. the next morning " . . . to be fully heard."

The next morning, Novopharm filed a motion requesting a concrete identification of the issue about which Novopharm was being required to present an offer of proof in order to be fully heard. Ignoring Novopharm's request, the district court refused to further identify the issue and expressly "found" that Novopharm had been fully heard. Judgment under Rule 50(a) was then entered against Novopharm.

Thus, after three and one-half weeks of trial, in which only BW presented evidence to the jury, the district court removed all issues in the case from the jury and entered judgment against Novopharm pursuant to *Fed.R.Civ.P.* 50(a). Novopharm never had the opportunity to present its case to the jury.

The judgment was based upon the district court's legal interpretation of the definition of "conception," an

element of inventorship. The district court stated the law of conception as it believed it to apply to the case:

> The law of conception as understood by the court is comprised of two elements. The first element relates to the state of mind of the inventor – whether he had a definite and permanent idea of the complete and operative invention. This element is subjective; so long as the idea is sufficiently defined and preserved, the law does not require that the inventor's idea be reasonable, scientifically accurate, or capable of being proved. This legal definition of the first element of conception is the object of the parties' current dispute and permeates the whole of the defendants' case.

App. at 36a.

The district court also articulated the role of the NIH scientists as a mere "pair of hands":

> The court notes further that a party who conducts tests wholly at the direction and instruction of another is merely a technician and not a conceiver and acts merely as a "pair of hands." The court finds that this last statement accurately characterizes the role played by Dr. Broder and Dr. Mitsuya. The evidence in the record shows that BW Co. sent Compound S to the NIH with specific instructions and directed the testing performed by Dr. Broder and Dr. Mitsuya.

App at 39a.

The Court of Appeals for the Federal Circuit rejected the district court's interpretation of the law of conception. The Federal Circuit recognized that scientific accuracy and reasonableness, and the ability of the idea to be proved, bear on conception, stating:

> A conception is not complete if the subsequent course of experimentation, especially experimental failures, reveals uncertainty that so undermines the specificity of the inventor's idea that it is not yet a definite and permanent reflection of the complete invention as it will be used in practice.

App. at 14a.

The Court of Appeals for the Federal Circuit proceeded to give credence to the evidence presented by BW to the jury, while ignoring the evidence presented by Novopharm in its offer of proof. The Appeals Court improperly affirmed the district court on five of the six patents in suit. The linchpin of the Federal Circuit's holding is a draft British patent application, prepared by BW before the critical NIH work:

> The '232, '838, '130, '208, and '538 patents encompass compositions and methods of using AZT to treat AIDS. The Burroughs Wellcome inventors claim conception of these inventions prior to the NIH experiments, based on the draft British patent application. That document is not itself a conception, for conception occurs in the inventors' minds, not on paper. The draft simply corroborates the claim that they had formulated a definite and permanent idea of the inventions by the time it was prepared.

App. at 16a.

REASONS FOR GRANTING THE PETITION

SUMMARY OF ARGUMENT

This case is unique. The party with the burden of proof on the only issue to be tried, here Novopharm, was forced to be "fully heard" by the submission of an offer of proof to the trial court. Novopharm never had the opportunity to present evidence to the jury. On appeal, Novopharm's evidence presented in its offer of proof should have been treated equally with the evidence presented to the jury. This did not happen. The Federal Circuit, after enunciating the controlling law, wholly ignored facts in Novopharm's offer of proof which bore directly on the issue of conception: experimental failures of others to show the activity of AZT against HIV, prior to the NIH's success, and the effect of those failures on the BW scientists' states of mind.

The Federal Circuit, by ignoring Novopharm's contrary evidence presented in the only manner allowed by the trial court – via an offer of proof – improperly usurped the role of the jury. The Federal Circuit failed to follow the guidelines of *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 106 S.Ct. 2505 (1986). *Anderson* requires not only that Novopharm's evidence be considered in the light most favorable to Novopharm but also that credibility determinations be made by the trier of fact. Instead, the Federal Circuit overstepped the proper role of an appellate court. Moreover, the Federal Circuit failed to apply its own case precedent holding that one who acts as more than a pair of hands should be accorded inventor status.

Through these errors, the Federal Circuit has so far departed from the accepted and usual course of judicial

proceedings that an exercise of this Court's supervisory power is necessary.

ARGUMENT

The district court's judgment under Rule 50(a) could have been affirmed only if, after examining the record in the light most favorable to Novopharm, and drawing all inferences in Novopharm's favor, the Federal Circuit concluded that the judgment entered was the only one possible under controlling law. In *Anderson*, 477 U.S. at 255, 106 S.Ct. 2513, this Court held that "[c]redibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of the judge, whether he is ruling on a motion for summary judgment or for a directed verdict. The evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor."

Under the standard for conception enunciated by the Federal Circuit in this case, Novopharm respectfully submits that there is sufficient evidence in the record to make the Federal Circuit's affirmance of the district court's judgment under Rule 50(a) wrong as a matter of law. Specifically, Novopharm presented evidence in its offer of proof that conception of the use of AZT to treat HIV was not complete until the NIH discovered that AZT was effective against HIV. This evidence consists of the utter failure of AZT to show any activity against HIV in experiments conducted by scientists at Duke University and at the FDA against the actual HIV. Those failures undermine any "conception" that may have existed prior to that

work, and destroy the corroborative value of BW's draft patent application.

A more detailed description of this evidence, which was included in Novopharm's offer of proof, and is included in the Appendix at 46a-52a, is set forth below.

I. Work Conducted at Duke and the FDA Showed that AZT Had No Activity Against HIV

In late November, 1984, after BW's St. Clair had reported positive results for AZT only in BW's mouse test, which used a mouse virus, not HIV, BW sent AZT to Dr. Quinnan, the Division Director of the Division of Virology in the Center for Biologies Evaluation at the FDA, to determine if AZT was actually active against HIV. Over the next three months, Quinnan reported several times to BW's Dr. Lehrman regarding the FDA's results. Each time, Quinnan reported that the FDA's results were equivocal, because insufficient data was generated for anyone to know whether AZT was reducing viral replication because it was toxic, or because it was acting as a "true antiviral." Thus, Quinnan's results revealed uncertainty in the BW scientists' idea that AZT would be effective against HIV.

The results BW received from Duke University were worse. On December 4, 1984, Dr. Lehrman forwarded a sample of AZT for testing against HIV to Dr. Weinhold at Duke. He immediately ran two assays, in which, as he reported to BW, AZT showed no activity. In fact, the results indicated that AZT was *toxic*. BW's St. Clair reported these results to her colleagues on February 1, 1985, a mere four days before the draft patent application

was completed. Weinhold next tested AZT on human cells that were newly infected with HIV. The early results, which again showed no activity, were reported to BW. It was not until approximately one month *after* Broder and Mitsuya of the NIH showed BW that AZT was active against HIV in human cells, that Weinhold first reported to BW that AZT had activity against HIV.

This evidence from Novopharm's offer of proof shows that prior to the work of the NIH, the idea that AZT would be effective against HIV was by no means definite and permanent. Just as in *Alpert v. Slatin*, 305 F.2d 891, 894 (C.C.P.A. 1962), where conception was not established until a reduction to practice occurred, the results BW received from its testers did not follow as BW speculated. Applying the standard for conception as enunciated by the Court of Appeals for the Federal Circuit, there is sufficient evidence upon which a jury could find that these experimental failures reveal uncertainty that so undermines the specificity of the BW scientists' idea that their idea cannot be definite and permanent prior to the NIH work. A jury could properly proceed to find a verdict for Novopharm, the party which had the burden of proof. It therefore was improper for the Court of Appeals for the Federal Circuit to affirm the lower court's judgment under Rule 50(a). *Anderson*, 477 U.S. at 255, 106 S.Ct. at 2513.

II. BW's Lack of a Definite and Permanent Idea is Evidenced By Its Actions

That BW's idea of using AZT to treat HIV was in flux, and not "definite and permanent," prior to the NIH's

work, is further evidenced by the stalled nature of BW's AZT project. Although BW's lawyers were working on a draft patent application, BW's scientists were waiting – waiting for some indication that AZT had activity against HIV. Only when that activity was reported to BW by the NIH's Broder did BW's effort to bring AZT to clinical trials begin. A more detailed description of this evidence, which was included in Novopharm's offer of proof, and is included here in the Appendix at 53a-58a, is set forth below.

Prior to receiving the positive results from the NIH, BW's AZT program was going nowhere fast. Clinical trials were on hold, awaiting the results from the NIH. BW had not yet formed a Project Group for AZT, or even proposed that one be formed. However, once Dr. Broder advised BW that AZT had shown activity against HIV, the attitude at BW changed. As BW's St. Clair stated, "[t]hings started happening so fast, that I kind of almost got lost behind". Clinical trials were started. A Project Group was formed.

Thus, work at BW on AZT went from almost none, prior to the NIH results, to a state of "full speed ahead", after those results were made known to BW. This is acknowledged by BW's Dr. Rideout, who stated:

> *Since the activity of AZT was reported to us by the NIH*, my group in the Organic Chemistry Department has worked full time on the synthesis of analogous and prodrugs of AZT to develop a patent position and to search for successors to AZT.

(emphasis added).

III. The Use of Rule 50(a) Was Error

Looking at the totality of the evidence, and using the standard of conception enunciated by the Court of Appeals for the Federal Circuit here, Novopharm respectfully submits that the district court's ruling under Rule 50(a) was wrong, as was the Federal Circuit's affirmation of that ruling. As Novopharm asserted in its offer of proof, prior to the work of the NIH showing that AZT was effective against HIV in human cells, BW had the following information:

(1) Activity of AZT only in mouse tests, which even BW admits is not predictive;

(2) Equivocal, unreliable results from the FDA that did not show AZT's activity against HIV; and

(3) Reports from Duke University that AZT showed no activity against HIV in two separate assays, and in tests using human cells, and that AZT may, in fact, be toxic to human cells.

Thus, Novopharm submits there is sufficient factual evidence upon which a jury could find that, prior to the NIH work, the idea that AZT would be effective against HIV was merely that – an idea, nothing definite, nothing permanent. It was a hope that so far had been crushed by the reality of the FDA and Duke work. There was true experimental uncertainty from the FDA and Duke work. This experimental uncertainty, i.e., whether AZT was in fact active against HIV, given the negative experimental results from Duke and the FDA, precludes a finding under Rule 50(a) that the BW scientists had a complete

conception prior to the work of the NIH and raises a factual inquiry for the jury.

IV. Because the NIH Scientists Were More Than a "Pair of Hands," They Should Have Been Afforded Coinventorship Status

In its Rule 50(a) judgment against Novopharm, the district court also found that NIH scientists, Dr. Broder and Dr. Mitsuya, were not entitled to joint inventor status because they acted as a mere "pair of hands," under the control of BW. The Federal Circuit, however, disagreed. It held that Drs. Broder and Mitsuya were much more than a mere "pair of hands." The court stated:

> That is not to say, however, that the NIH scientists merely acted as a "pair of hands" for the Burroughs Wellcome inventors. Broder and Mitsuya exercised considerable skill in conducting the tests, using their patented cell line to model the responses of human cells infected with HIV. Lehrman did suggest initial concentrations to Broder, but she hardly controlled the conduct of the testing, which necessarily involved interpretation of results for which Broder and Mitsuya, and very few others, were uniquely qualified.

App. at 18a.

Once the Federal Circuit held that the NIH scientists were more than a "pair of hands," it should have conferred joint inventorship status to Drs. Broder and Mitsuya for contributing to the conception of the invention. Under its own precedent, conception is only complete when one of ordinary skill in the art can reduce the

invention to practice without extensive research or experimentation. *Sewall v. Walters*, 21 F.3d 411, 415 (Fed.Cir. 1994).

The Federal Circuit however, failed to do so. This is the first time that a contributor to an invention who has been found to be more than a mere pair of hands in reducing an invention to practice has not been afforded appropriate status as a coinventor.

The reason why there has been no such case is apparent. It simply is not possible to be more than a pair of hands, i.e. to exercise inventive skill, without also being a joint inventor. *Sewall*, 21 F.3d at 415; *Land v. Dreyer*, 155 F.2d 383, 387 (C.C.P.A. 1946).

CONCLUSION

For all of the foregoing reasons, Novopharm respectfully requests that the Court issue a writ of certiorari to review the judgment of the Court of Appeals for the Federal Circuit.

Respectfully submitted,

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United States Court of Appeals
for the Federal Circuit

93-1503, -1504, -1505

BURROUGHS WELLCOME CO.,

Plaintiff-Appellee,

v.

BARR LABORATORIES, INC.,

Defendant-Appellant,

and

NOVOPHARM, INC. and NOVOPHARM, LTD.,

Defendants-Appellants.

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Dan K. Webb, Winston & Strawn, of Chicago, Illinois, argued for defendant-appellant. With him on the brief were *Eric L. Hirschhorn, George C. Lombardi, James F. Hurst* and *Monique M. Vasilchik.* Also on the brief were *Myron Cohen* and *Michael C. Stuart,* Cohen, Pontani, Lieberman & Pavane, of New York, New York. *Robert F. Green,* Leydig, Voit & Mayer, LTD., of Chicago, Illinois, argued for defendants-appellants. With him on the brief were

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Appealed from: U.S. District Court for the
Eastern District of North Carolina

Judge Howard

United States Court of Appeals
for the Federal Circuit

93-1503, -1504, -1505

BURROUGHS WELLCOME CO.,

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Defendant-Appellant,

and

NOVOPHARM, INC. and NOVOPHARM, LTD.,

Defendants-Appellants.

DECIDED: November 22, 1994

Before MAYER, LOURIE, and SCHALL, *Circuit Judges.*

MAYER, *Circuit Judge.*

Barr Laboratories, Inc., Novopharm, Inc., and Novopharm, Ltd., appeal the order of the United States District Court for the Eastern District of North Carolina, *Burroughs Wellcome Co. v. Barr Lab., Inc.,* 828 F. Supp. 1208

(E.D.N.C. 1993), granting the motion of Burroughs Wellcome Co. for judgment as a matter of law that six United States patents were not invalid and were infringed. We affirm in part, vacate in part, and remand.

Background

Burroughs Wellcome Co. is the owner of six United States patents that cover various preparations of 3'-azidothymidine (AZT) and methods for using that drug in the treatment of persons infected with the human immunodeficiency virus (HIV).[1] Each of these patents names the same five inventors – Janet Rideout, David Barry, Sandra Lehrman, Martha St. Clair, and Phillip Furman (Burroughs Wellcome inventors) – all of whom were employed by Burroughs Wellcome at the time the inventions were alleged to have been conceived. The defendants-appellants concede that all five are properly named as inventors on the patents.

Burroughs Wellcome's patents arise from the same parent application filed on September 17, 1985.[2] Five of

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[1] Although two of the patents claim pharmaceutical compositions of AZT, not methods of treatment per se, the parties treat all of the patents as covering the particular use of AZT as a treatment for AIDS and its symptoms. The district court adopted this interpretation and applied the patents as though all claimed methods of treatment; no party argues for another interpretation, so we do the same.

[2] The following patents are at issue: U.S. Patent No. 4,724,232 (the '232 patent), filed September 17, 1985, issued February 9, 1988; No. 4,828,838 (the '838 patent), filed October 21, 1987, issued May 9, 1989; No. 4,833,130 (the '130 patent), filed October 20, 1987, issued May 23, 1989; No. 4,837,208 (the

the patents relate to the use of AZT to treat patients infected with HIV or who have acquired immunodeficiency syndrome (AIDS).[3] The other patent, the '750 patent, covers a method of using AZT to increase the T-lymphocyte count of persons infected with HIV.[4]

'208 patent), filed October 20, 1987, issued June 6, 1989; No. 4,818,538 (the '538 patent), filed October 21, 1987, issued April 4, 1989; and No. 4,818,750 (the '750 patent), filed October 20, 1987, issued April 4, 1989.

[3] Claim 1 of the '232 patent covers "[a] method of treating a human having acquired immunodeficiency syndrome comprising the oral administration of an effective acquired immunodeficiency syndrome treatment amount of 3'-azido-3'-deoxythymidine to said human."

Claim 1 of the '838 patent covers "[a] pharmaceutical preparation comprising a capsule containing 5 to 500 mg of 3'-azido-3'-deoxythymidine."

Claim 1 of the '130 patent covers "[a] method of treating a human having an HTLV III virus infection comprising administering to said human an effective HTLV III virus treatment amount of 3'-azido-3'-deoxythymidine."

Claim 1 of the '208 patent covers "[a] method of treating a human having antibodies to the HTLV III virus which comprises administering to said human an effective HTLV III treatment amount of 3'-azido-3'-deoxythymidine."

Claim 1 of the '538 patent covers "[a] sealed container including a pharmaceutical composition in unit dosage form comprising 5 to 500 mg of 3'-azido-3'-deoxythymidine together with a pharmaceutically acceptable solid carrier."

[4] Claim 1 of the '750 patent covers "[a] method of increasing the number of T-lymphocytes in a human infected with the HTLV III virus comprising administering to said human an effective amount of 3'-azido-3'-deoxythymidine or a pharmaceutically acceptable alkali metal, alkaline earth or ammonium salt thereof."

In the early 1980s, scientists began to see patients with symptoms of an unknown disease of the immune system, now known as AIDS. The disease attacks and destroys certain white blood cells known as CD4 T-lymphocytes or T-cells, which form an important component of the body's immune system. The level of destruction eventually becomes so great that the immune system is no longer able to mount an effective response to infections that pose little threat to a healthy person.

In mid-1984, scientists discovered that AIDS was caused by a retrovirus, known as HTLV III or, more commonly today, HIV. After the identification of HIV, Burroughs Wellcome began to search for a cure, screening compounds for antiretroviral activity using two murine (or mouse) retroviruses, the Friend leukemia virus and the Harvey sarcoma virus.

At about this time, scientists at the National Institutes of Health (NIH), led by Samuel Broder, were looking for effective AIDS therapies as well. Unlike Burroughs Wellcome, Broder and his colleagues used live HIV, and were able to develop a test that could demonstrate a compound's effectiveness against HIV in humans using a unique line of T-cell clones (the ATH8 cell line). The NIH scientists began to seek compounds from private pharmaceutical companies for screening in their cell line. After Burroughs Wellcome contacted Broder in the fall of 1984, he agreed to accept compounds from Burroughs Wellcome under code for testing against live HIV.

Burroughs Wellcome's Rideout selected AZT and a number of other compounds for testing in the murine screens on October 29, 1984. The tests, performed at

Burroughs Wellcome facilities by St. Clair, showed that AZT had significant activity against both murine retroviruses at low concentrations. In light of these positive results, the Burroughs Wellcome inventors met on December 5, 1984, to discuss patenting the use of AZT in the treatment of AIDS. Burroughs Wellcome's patent committee thereafter recommended that the company prepare a patent application for future filing. By February 6, 1985, the company had prepared a draft application filing in the United Kingdom. The draft disclosed using AZT to treat patients infected with HIV, and set out various pharmaceutical formulations of the compound in an effective dosage range to treat HIV infection.

Two days earlier, on February 4, 1985, Burroughs Wellcome had sent a sample of AZT, identified only as Compound S, to Broder at NIH. In an accompanying letter, Lehrman told Broder of the results of the murine retrovirus tests and asked that he screen the compound for activity against HIV in the ATH8 cell line. Another NIH scientist, Hiroaka Mitsuya, performed the test in mid-February 1985, and found that Compound S was active against HIV. Broder informed Lehrman of the results by telephone on February 20, 1985. Burroughs Wellcome filed its patent application in the United Kingdom on March 16, 1985.

After Burroughs Wellcome learned that AZT was active against HIV, it began the process of obtaining Food and Drug Administration (FDA) approval for AZT as an AIDS therapy. As a part of the clinical trials leading to FDA approval, Broder and another NIH scientist, Robert Yarchoan, conducted a Phase I human patient study which showed that treatment with AZT could result in an

increase in the patient's T-cell count. Broder reported this result to Lehrman on July 23, 1985. In 1987, the FDA approved AZT for marketing by Burroughs Wellcome; Burroughs Wellcome markets the drug for treatment of HIV infection under the trademark Retrovir.

On March 19, 1991, Barr Laboratories, Inc. (Barr) sought FDA approval to manufacture and market a generic version of AZT by filing an Abbreviated New Drug Application (ANDA) pursuant to 21 U.S.C. § 355(j) (1988). As part of the process, Barr certified to the FDA that Burroughs Wellcome's patents were invalid or were not infringed by the product described in its ANDA. After Barr informed Burroughs Wellcome of its action, Burroughs Wellcome commenced this case for patent infringement against Barr on May 14, 1991, alleging technical infringement of its patents under 35 U.S.C. § 271(e)(2)(A) (1988).

Barr filed a counterclaim under 35 U.S.C. § 256 (1988) seeking correction of the patents to list Broder and Mitsuya as coinventors. Barr admitted that its AZT product would infringe the patents, but contended that it did not because Barr had obtained a license to manufacture and sell AZT from the government, which should be deemed the owner of the interest of coinventors Broder and Mitsuya in the AZT patents. Burroughs Wellcome denied that Broder and Mitsuya were coinventors and also responded that the assertion of any rights of Broder, Mitsuya, or the government in the patents was barred by laches, estoppel, and waiver.

Thereafter, Novopharm, Ltd. filed an ANDA of its own, seeking approval to manufacture and market its

generic version of AZT. Burroughs Wellcome filed infringement suits against Novopharm, Ltd. and its American subsidiary Novopharm, Inc., which were consolidated with the suit against Barr.[5] Like Barr, Novopharm, Ltd. admitted that its AZT product would infringe the claims of the six patents, but for the failure of Burroughs Wellcome to name the NIH scientists as coinventors of the subject matter of the patents. Although Novopharm, Inc. agreed to be bound by any injunction issued against its parent, it argued that it had not infringed the patents because it had not filed an ANDA and had no AZT product of its own.[6] Novopharm contended that Broder and Mitsuya should have been named as inventors on five of the patents, and contended that Broder and Yarchoan were coinventors of the '750 patent. It maintained that the patents were invalid because of the alleged nonjoinder, and because Burroughs Wellcome had omitted the coinventors with deceptive intent, the patents were unenforceable for inequitable conduct.

After more than three weeks of trial while Burroughs Wellcome was still in the process of presenting its case,

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[5] Novopharm, Inc. and Novopharm, Ltd. are jointly represented by counsel and make many of the same arguments on appeal. Except where it is more appropriate to refer to them individually, we will refer to them together as Novopharm.

[6] Burroughs Wellcome alleges that Novopharm, Inc. is liable for the infringement by Novopharm, Ltd. on grounds that it participated in or induced Novopharm, Ltd.'s infringing activities. But Burroughs Wellcome had the burden of proving infringement by Novopharm, Inc. and on the record before us there is simply no evidence to support a conclusion on this factual question. The judgment against Novopharm, Inc. is vacated.

the district court granted Burroughs Wellcome's motion for judgment as a matter of law against all of the defendants, concluding that the Burroughs Wellcome inventors had conceived of the subject matter of the inventions at some time before February 6, 1985, without the assistance of Broder, Mitsuya, or Yarchoan. The court rejected the arguments of Barr and Novopharm that they should be allowed to present evidence that the Burroughs Wellcome inventors had no reasonable belief that the inventions would actually work – that AZT was in fact active against HIV – until they were told the results of the NIH testing.

The court also rejected Novopharm's argument that the Burroughs Wellcome inventors had not conceived the invention of the '750 patent – the use of AZT to increase a patient's T-cell count – before July 23, 1985, when Broder reported the results of the NIH patient study to Lehrman. The court concluded that the increase in T-cell count was an obvious phenomenon known to the inventors that would result from administration of AZT. And the district court denied Barr's renewed motion for partial summary judgment on Burroughs Wellcome's equitable defenses to its counterclaim for correction of the patents under section 256.

Discussion

The arguments of both Barr and Novopharm are directed to when the inventors conceived the invention. Burroughs Wellcome says it was before they learned the results of the NIH tests; Barr and Novopharm say that confirmation of the inventions' operability, which came from the NIH tests, was an essential part of the inventive

process. If Burroughs Wellcome is right, then the patents name the proper inventors, they are not invalid, and the appellants are liable for infringement. If Barr and Novopharm are correct, then Broder, Mitsuya, and Yarchoan should have been named as joint inventors and the resolution of Burroughs Wellcome's infringement suits is premature.

The district court's grant of judgment as a matter of law under Rule 50(a) is subject to de novo review. *Read Corp. v. Portec, Inc.*, 970 F.2d 816, 821, 23 USPQ2d 1426, 1431 (Fed. Cir. 1992). We must apply the same standard as did that court, examining the record in the light most favorable to the nonmovant and drawing inferences in that party's favor. We may affirm only if the judgment entered was the only one possible under the controlling law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986).

A joint invention is the product of a collaboration between two or more persons working together to solve the problem addressed. 35 U.S.C. § 116 (1988); *Kimberly-Clark Corp. v. Procter & Gamble Distrib. Co.*, 973 F.2d 911, 917, 23 USPQ2d 1921, 1926 (Fed. Cir. 1992). People may be joint inventors even though they do not physically work on the invention together or at the same time, and even though each does not make the same type or amount of contribution. 35 U.S.C. § 116. The statute does not set forth the minimum quality or quantity of contribution required for joint inventorship.

Conception is the touchstone of inventorship, the completion of the mental part of invention. *Sewall v. Walters*, 21 F.3d 411, 415, 30 USPQ2d 1356, 1359 (Fed. Cir.

1994). It is "the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376, 231 USPQ 81, 87 (Fed. Cir. 1986) (citation omitted). Conception is complete only when the idea is so clearly defined in the inventor's mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation. *Sewall*, 21 F.3d at 415, 30 USPQ2d at 1359; *see also Coleman v. Dines*, 754 F.2d 353, 359, 224 USPQ 857, 862 (Fed. Cir. 1985) (conception must include every feature of claimed invention). Because it is a mental act, courts require corroborating evidence of a contemporaneous disclosure that would enable one skilled in the art to make the invention. *Coleman v. Dines*, 754 F.2d at 359, 224 USPQ at 862.

Thus, the test for conception is whether the inventor had an idea that was definite and permanent enough that one skilled in the art could understand the invention; the inventor must prove his conception by corroborating evidence, preferably by showing a contemporaneous disclosure. An idea is definite and permanent when the inventor has a specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan he hopes to pursue. *See Fiers v. Revel*, 984 F.2d 1164, 1169, 25 USPQ2d 1601, 1605 (Fed. Cir. 1993); *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1989) (no conception of chemical compound based solely on its biological activity). The conception analysis necessarily turns on the inventor's ability to describe his invention with particularity. Until he can do so, he cannot prove possession of

the complete mental picture of the invention. These rules ensure that patent rights attach only when an idea is so far developed that the inventor can point to a definite, particular invention.

But an inventor need not know that his invention will work for conception to be complete. *Applegate v. Scherer*, 332 F.2d 571, 573, 141 USPQ 796, 799 (CCPA 1964). He need only show that he had the idea; the discovery that an invention actually works is part of its reduction to practice. *Id.; see also Oka v. Youssefyeh*, 849 F.2d 581, n.1, 7 USPQ2d 1169, 1171 n.1 (Fed. Cir. 1988).

Barr and Novopharm suggest that the inventor's definite and permanent idea must include a reasonable expectation that the invention will work for its intended purpose. They argue that this expectation is of paramount importance when the invention deals with uncertain or experimental disciplines, where the inventor cannot reasonably believe an idea will be operable until some result supports that conclusion. Without some experimental confirmation, they suggest, the inventor has only a hope or an expectation, and has not yet conceived the invention in sufficiently definite and permanent form. But this is not the law. An inventor's belief that his invention will work or his reasons for choosing a particular approach are irrelevant to conception. *MacMillan v. Moffett*, 432 F.2d 1237, 1239, 167 USPQ 550, 552 (CCPA 1970).

To support their reasonable expectation rule, Barr and Novophharm point to a line of cases starting with *Smith v. Bousquet*, 111 F.2d 157, 45 USPQ 347 (CCPA 1940),

establishing the so-called doctrine of simultaneous conception and reduction to practice.[7] *Smith* was an interference priority contest between alleged inventors of the use of two known compounds as insecticides. Both parties asserted priority based on testing of the compounds against selected insect species. Noting the unpredictability of the experimental sciences of chemistry and biology, in particular the uncertain relationship between chemical structure and biological activity, *Smith* declined to find conception until the invention had been reduced to practice by the filing of the first patent application. *Id.* at 162, 45 USPQ at 352. Barr and Novopharm read this and subsequent cases to establish, or at lest support, their rule that conception of an invention in an unpredictable field occurs only when the inventor has reasonable grounds to believe the invention will work.

But these cases do not stand for the proposition that an inventor can never conceive an invention in an unpredictable or experimental field until reduction to practice. In rejecting the asserted evidence of conception, *Smith* said as to one of the compounds:

> it is apparent from the record that neither [party] had in mind at the time the suggestions were originally made, nor at any time thereafter, until successful tests, if any, were made, what insects, if any, it might be effective against, or

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[7] Barr and Novopharm also point to dictum in *Biel v. Chessin*, 347 F.2d 898, 146 USPQ 293 (CCPA 1965), suggesting that conception of a method of treating the human body requires a reasonable understanding that the method will work for its intended purpose. No court has applied this dictum as controlling, and we decline to do so here.

> how it might be applied to produce the desired results. Accordingly, neither party had a definite idea of the "complete and operative invention" here involved prior to a successful reduction – actual or constructive – of it to practice.

Id. Thus, in awarding priority to Smith based on his constructive reduction to practice, the court relied not on the inherent unpredictability of the science, but on the absence of any evidence to corroborate an earlier conception for either of the parties.

It is undoubtedly true that "[i]n some instances, an inventor is unable to establish a conception until he has reduced the invention to practice through a successful experiment." *Amgen*, 927 F.2d at 1206, 18 USPQ2d at 1021; *Alpert v. Slatin*, 305 F.2d 891, 894, 134 USPQ 296, 299 (CCPA 1962) (no conception "where results at each step do not follow as anticipated, but are achieved empirically by what amounts to trial and error"). But in such cases, it is not merely because the field is unpredictable: the alleged conception fails because, as in *Smith*, it is incomplete. Then the event of reduction to practice in effect provides the only evidence to corroborate conception of the invention.

Under these circumstances, the reduction to practice can be the most definitive corroboration of conception, for where the idea is in constant flux, it is not definite and permanent. A conception is not complete if the subsequent course of experimentation, especially experimental failures, reveals uncertainty that so undermines the specificity of the inventor's idea that it is not yet a definite and permanent reflection of the complete invention as it will be used in practice. *See Amgen*, 927 F.2d at 1207, 18

USPQ2d at 1021 (no conception until reduction to practice where others tried and failed to clone gene using suggested strategy); *Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 1387, 181 USPQ 453, 457-58 (CCPA 1974) (focusing on nature of subsequent research as indicator that inventors encountered no perplexing intricate difficulties). It is this factual uncertainty, not the general uncertainty surrounding experimental sciences, that bears on the problem of conception.

Barr and Novopharm argue for a broader reading of *Amgen* and *Fiers* in support of their reasonable expectation rule. Both of these cases involve conception of a DNA encoding a human protein – a chemical compound. Conception of a chemical substance includes knowledge of both the specific chemical structure of the compound and an operative method of making it. *Fiers*, 984 F.2d at 1169, 25 USPQ2d at 1604; *Amgen*, 927 F.2d at 1206, 18 USPQ2d at 1021; *Oka*, 849 F.2d at 583, 7 USPQ2d at 1171. The alleged inventors in *Fiers* and *Amgen* claimed conception of their respective inventions before they knew relevant chemical structure – the nucleotide sequence – so the courts found no conception until experimentation finally revealed that structure. Here, though, Burroughs Wellcome's inventions use a compound of known structure; the method of making the compound is also well known.

We emphasize that we do not hold that a person is precluded from being a joint inventor simply because his contribution to a collaborative effort is experimental. Instead, the qualitative contribution of each collaborator is the key – each inventor must contribute to the joint arrival at a definite and permanent idea of the invention as it will be used in practice.

Nor do we suggest that a bare idea is all that conception requires. The idea must be definite and permanent in the sense that it involves a specific approach to the particular problem at hand. It must also be sufficiently precise that a skilled artisan could carry out the invention without undue experimentation. And, of course, the alleged conception must be supported by corroborating evidence. On the facts before us, it is apparent that the district court correctly ruled against Barr and Novopharm as to five of the patents, but that the court's judgment as to the sixth, the '750 patent, was premature.

The '232, '838, '130, '208, and '538 patents encompass compositions and methods of using AZT to treat AIDS. The Burroughs Wellcome inventors claim conception of these inventions prior to the NIH experiments, based on the draft British patent application. That document is not itself a conception, for conception occurs in the inventors' minds, not on paper. The draft simply corroborates the claim that they had formulated a definite and permanent idea of the inventions by the time it was prepared.

The Burroughs Wellcome inventors set out with the general goal of finding a method to treat AIDS, but by the time Broder confirmed that AZT was active against HIV, they had more than a general hope or expectation. They had thought of the particular antiviral agent with which they intended to address the problem, and had formulated the idea of the inventions to the point that they could express it clearly in the form of a draft patent application, which Barr and Novopharm concede would teach one skilled in the art to practice the inventions. The draft expressly discloses the intended use of AZT to treat AIDS. It sets out the compound's structure, which, along

with at least one method of preparation, was already well known. The draft also discloses in detail both how to prepare a pharmaceutical formulation of AZT and how to use it to treat a patient infected with HIV. The listed dosages, dose forms, and routes of administration conform to those eventually approved by the FDA. The draft shows that the idea was clearly defined in the inventors' minds; all that remained was to reduce it to practice – to confirm is operability and bring it to market. *See Haskell v. Colebourne,* 671 F.2d 1362, 1365-66, 213 USPQ 192, 194 (CCPA 1982) (enabling draft patent application sufficient to corroborate conception).

An examination of the events that followed the preparation of Burroughs Wellcome's draft confirms the soundness of the conception. Broder and Mitsuya received from Burroughs Wellcome a group of compounds, known to Broder and Mitsuya only by code names, selected for testing by the Burroughs Wellcome inventors. They then tested those compounds for activity against HIV in their patented cell line. The test results revealed for the first time that one of the compounds, later revealed to be AZT, was exceptionally active against the virus.

Here, though, the testing was brief, simply confirming that operability of what the draft application disclosed. True, the science surrounding HIV and AIDS was unpredictable and highly experimental at the time the Burroughs Wellcome scientists made the inventions. But what matters for conception is whether the inventors had a definite and permanent idea of the operative inventions. In this case, no prolonged period of extensive research, experiment, and modification followed the

alleged conception. By all accounts, what followed was simply the normal course of clinical trials that mark the path of any drug to the marketplace.

That is not to say, however, that the NIH scientists merely acted as a "pair of hands" for the Burroughs Wellcome inventors. Broder and Mitsuya exercised considerable skill in conducting the tests, using their patented cell line to model the responses of human cells infected with HIV. Lehrman did suggest initial concentrations to Broder, but she hardly controlled the conduct of the testing, which necessarily involved interpretation of results for which Broder and Mitsuya, and very few others, were uniquely qualified. But because the testing confirmed the operability of the inventions, it showed that the Burroughs Wellcome inventors had a definite and permanent idea of the inventions. It was part of the reduction to practice and inured to the benefit of Burroughs Wellcome.

Barr and Novopharm allege error in the district court's refusal to hear their evidence of the poor predictive value of the murine retrovirus screens for activity against HIV. Regardless of the predictive value of the murine tests, however, the record shows that soon after those tests, the inventors determined, for whatever reason, to use AZT as a treatment for AIDS, and they prepared a draft patent application that specifically set out the inventions, including an enabling disclosure. Obviously, enablement and conception are distinct issues, and one need not necessarily meet the enablement standard of 35 U.S.C. § 112 to prove conception. *See Fiers*, 984 F.2d at 1169, 25 USPQ2d at 1605. But the enabling disclosure does suffice in this case to confirm that the inventors had

concluded the mental part of the inventive process – that they had arrived at the final, definite idea of their inventions, leaving only the task of reduction to practice to bring the inventions to fruition.

The question is not whether Burroughs Wellcome reasonably believed that the inventions would work for their intended purpose, the focus of the evidence offered by Barr and Novopharm, but whether the inventors had formed the idea of their use for that purpose in sufficiently final form that only the exercise of ordinary skill remained to reduce it to practice. *See MacMillan v. Moffett*, 432 F.2d at 1239, 167 USPQ at 552 (Inventor's "reasons or lack of reasons for including U-5008 are not relevant to the question of conception. The important thing is that he did think in definite terms of the method claimed."). Whether or not Burroughs Wellcome believed the inventions would in fact work based on the mouse screens is irrelevant.

We do not know precisely when the inventors conceived their inventions, but the record shows that they had done so by the time they prepared the draft patent application that thoroughly and particularly set out the inventions as they would later be used. The district court correctly ruled that on this record, the NIH scientists were not joint inventors of these inventions.

The '750 patent is another question. It claims "[a] method of increasing the number of T-lymphocytes in a human infected with the [HIV] virus comprising administering to said human an effective amount of" AZT. Novopharm argues that there is no evidence, under any

test of inventorship, that the Burroughs Wellcome inventors conceived of this invention until after the Phase I patient study conducted by Broder and Yarchoan revealed that AZT could lead to increased levels of T-cells in AIDS patients.

Novopharm is right that the record is devoid of any statement that the inventors thought AZT could raise a patient's T-cell levels, but evidence need not always expressly show possession of the invention to corroborate conception. The district court held that the record supported conception as a matter of law, concluding that "an increase in T-lymphocyte count was an 'obvious,' natural phenomenon known to the [Burroughs Wellcome] inventors that would result from the inhibition of a retrovirus." *Burroughs Wellcome Co. v. Barr Lab., Inc.*, 828 F. Supp. at 1213. Burroughs Wellcome argues that this conclusion was proper because increased T-cell count is simply an obvious property or use of the greater discovery at issue here, the treatment of HIV infection with AZT. Because an increase in T-lymphocytes follows inevitably from treatment of AIDS patients with AZT, Burroughs Wellcome says, Broder and Yarchoan merely observed that the method invented by the Burroughs Wellcome inventors had qualities that the inventors failed to perceive. Burroughs Wellcome says this is not an inventive contribution to the claims of any of the AZT patents.

But even though all six patents arise from the same parent application and are subject to terminal disclaimers to avoid rejection for obviousness-type double patenting,

each patent claims a different invention.[8] *See In re Longi*, 759 F.2d 887, 892, 225 USPQ 645, 648 (Fed. Cir. 1985) (inventor can get only one patent for any single invention). It is true that the Patent Office determined that the method of the '750 patent would have been obvious to those skilled in the art in light of the inventions claimed in the other patents. That is, however, irrelevant to the question whether the Burroughs Wellcome inventors had conceived of the invention before they learned the results of the Phase I trials. For conception, we look not to whether one skilled in the art could have thought of the invention, but whether the alleged inventors actually had in their minds the required definite and permanent idea. *Cf. Bosies v. Benedict*, 27 F.3d 539, 543, 30 USPQ2d 1862, 1865 (Fed. Cir. 1994) (testimony of noninventor as to noninventor's understanding of inventor's written formula insufficient to prove conception). The record does not now support resolution of this question as a matter of law.

The alleged conception is supported by testimony of Burroughs Wellcome's experts, Burroughs Wellcome's

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[8] We must assume for the purposes of this case that the '750 patent is drawn to an invention different from each of the other five patents. The parties do not ask us to decide whether claims drawn to an effect or mechanism of action of AZT – its ability to raise T-cell count – reach the same invention as (that is, are inherent in) claims drawn to use of the drug to treat HIV infection or AIDS, and we express no opinion on that. The dissent therefore goes beyond the issues presented and the record before us to decide on the basis of what the dissenting judge thinks he knows. That is not the role of an appellate court.

draft Phase I protocol, and the same draft patent application that corroborates conception of the other five inventions. The experts testified that those skilled in the art at the time expected increased immune function to accompany inhibition of HIV. The draft patent application discloses that HIV preferentially destroys T-cells, that AIDS is associated with progressive depletion of T-cells, and that AZT is an effective treatment for HIV infection. Finally, the draft protocol directs the administrators of the Phase I study to monitor patients' T-lymphocyte count. This evidence supports an inference that the Burroughs Wellcome inventors did have the necessary definite and permanent idea, for, given the virus' effect on T-lymphocytes, it seems logical to conclude that stopping the virus might reverse the process of T-cell destruction and restore the body's immune system to a pre-infection state. If this were the only evidence in the record, the court's judgment would be sustained.

But Novopharm offered evidence suggesting that one skilled in the art would not have expected T-cell count to rise. On deposition, Broder testified that prior to the first patient study, "no one knew whether there was such a thing as recovery" of T-cells, based on the NIH's experience with suramin, a drug that entered clinical trials before AZT. Although suramin showed some activity against HIV, inhibition of the retrovirus apparently was not accompanied by increases in T-cell count or restoration of immune functions. Of course, there might be any number of other explanations for the results of the suramin trials; but they might suggest that although those skilled in the art recognized the significance of T-lymphocyte levels in HIV infection and AIDS, they might have

expected inhibition of the virus simply to halt the continuing destruction of T-cells, not to increase T-cell count and restore immune function. This could support an inference that the inventors themselves did not conceive the invention prior to the Phase I study.

Novopharm also contends that Burroughs Wellcome prepared its Phase I protocol in collaboration with Broder and the NIH, possibly from a draft protocol prepared by Broder and Yarchoan pursuant to their study of suramin. These contentions are relevant to the conception inquiry for they tend to undermine the corroborative value of the draft protocol, and might even support joint inventorship based on that draft. *See Coleman v. Dines*, 745 F.2d at 360, 224 USPQ at 863 (document's co-author cannot be considered sole inventor of invention disclosed in document without further proof). Because under Rule 50(a) all inferences must be taken against the moving party, the court's ruling on the '750 patent was inappropriate, and we vacate the judgment to that extent and remand for further proceedings.

Conclusion

Accordingly, the judgment of the United States District Court for the Eastern District of North Carolina is affirmed in part, vacated in part, and remanded.

COSTS

All parties will bear their own costs.

AFFIRMED IN PART, VACATED IN PART, AND REMANDED

United States Court of Appeals for the Federal Circuit

93-1503, -1504, -1505

BURROUGHS WELCOME CO.,
Plaintiff-Appellee,

v.

BARR LABORATORIES, INC.,
Defendant-Appellant,

and

NOVOPHARM, INC. and NOVOPHARM, LTD.,
Defendants-Appellants.

LOURIE, *Circuit Judge*, concurring-in-part and dissenting-in-part.

I concur in the majority's decision with respect to the '232, '838, '130, '208, and '538 patents, and join the opinion except for the following:

I do not agree that reduction to practice is corroboration of conception and that the completeness of a conception is affected by subsequent experimental success or failure. These statements confuse the idea of conception with both corroboration and reduction to practice. A conception must be judged as to its completeness in relation to the invention being claimed. It must also be corroborated by evidence independent of the inventor. If subsequent experimentation shows that an invention that was only conceived does not work, that fact does not vitiate the earlier conception. A conception not later reduced to practice may have little significance, but it is important that we not confuse concepts. The conception was still a conception. It is of course possible for an invention to be

reduced to practice constructively, *i.e.*, by filing a patent application, rather than actually, by doing the work, in which case the reduction to practice clearly says nothing about the completeness of the conception. Moreover, what matters, in addition to the completeness of a conception, is its date. Corroboration must be of the date of the conception. If the only "corroboration" of the conception is its reduction to practice, corroboration has not occurred concerning the alleged date of conception. Finally on this point, reduction to practice by the inventor is not corroboration because corroboration must be independent of the inventor. Corroboration is not a demonstration that the conceived invention works; it is evidentiary proof that the mental act of invention occurred on a certain date.

I also believe that the issue of joint inventorship is irrelevant here and therefore confusing. If the Burroughs Wellcome inventors had a complete conception, as we hold, then the NIH scientists were not inventors because the invention had already been made, not because of any shortcomings in their inventive contributions. Thus, there is no need to discuss joint inventorship at all.

I respectfully dissent from the vacating of the court's judgment concerning the '750 patent. I believe that the method of the '750 patent is an inherent, inevitable result of the practice of the other method patents claiming treatment of HIV or AIDS. It seems to be the (or a) mechanism by which the other methods find their use.

Even if it is true that the first verification or articulation of the increase in the T-cell count occurred in the hands of NIH scientists, this finding inures to the benefit

of those who conceived the method of treatment that led to it. The method of the '750 patent is merely a refined definition of the method of the '232 patent, which issued from the original application. The '130 and '208 patents, which also came from applications later filed with the '750 and the composition patents, are also modifications of the original filing. It is common practice for applicants to claim all aspects of their invention and that is what appears to have happened here. An inventor is entitled to the inherent benefits that flow from his or her invention. It is improper to split the inventorship of what is one invention merely because the means by which it was achieved was later verified by scientists acting pursuant to the original conceivers.

The PTO of course issued these patents. During its examination, it determined that the '750 method was obvious over the '232 method. Given a terminal disclaimer, this led to the grant of the patent. More than being obvious, however, the method was inherent in the '232 method and therefore lacking in novelty. *See* 35 U.S.C. §102 (1988). If, as I believe, the '750 invention does lack novelty over the other patents, its validity may be in question on the ground of double patenting because a terminal disclaimer is not effective to cure a double patenting problem when the inventions are the same. As long as the inventive entities are also the same, however, it doesn't really matter.

Even assuming that the '750 method is a separate invention, the majority concedes that evidence supports an inference that the Burroughs Wellcome inventors alone conceived the method. The majority goes off the track, however, in relying on Novopharm's offer of evidence

that one would not have expected the T-cell count to rise. This is irrelevant if Burroughs Wellcome's inventors had the conception, because the opinion earlier correctly holds that a reasonable expectation of success is not necessary to a conception.

The majority here is inviting the trial court on remand and motion, *see* 35 U.S.C. §256 (1988), to partially split the inventorship, and presumably also the ownership, of this related collection of patents claiming the physical act of "treating" and the result which the treatment accomplishes. This makes no sense. It amounts to deciding that treating a person in pain with aspirin is one invention and invoking the pain-relieving mechanism by means of that treatment is another. One cannot apparently treat HIV-infected humans with AZT without also increasing the level of T-lymphocytes. The panel is thus inconsistent in upholding the conclusion of the trial court that Burroughs Wellcome's scientists alone conceived the invention of using AZT to treat HIV infection, but then failing to arrive at the same conclusion regarding a patent claiming one of the sequelae of that use.

The real result of the majority's vacating the court's decision on the '750 patent is that, while it may believe that it is affirming the decision on the other patents, it may in practical effect be destroying Burroughs Wellcome's exclusivity for its invention and creating a whole new set of questions. If the trial court joins the NIH inventors, and NIH has licensed the patent to companies intending to sell AZT, will those companies infringe the '232 and other patents? Is the terminal disclaimer still valid, lacking the consent of one of the assignees? Without a valid terminal disclaimer, is the '750 patent valid?

While these questions are not before us, exploring them illustrates the strange consequences of the majority's decision. On the other hand, if the trial court confirms its finding that the T-lymphocyte "invention" was essentially the same invention and inured to the benefit of Burroughs Wellcome, the remand will have been superfluous. Useless and inefficient litigation and burdening of the courts will have resulted.

The trial court's decision should be affirmed across the board because it correctly found that the Burroughs Wellcome inventors solely conceived and are entitled to the inventive benefit of all the claimed inventions.

THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
NEW BERN DIVISION

BURROUGHS WELLCOME CO., Plaintiff, v. BARR LABORATORIES, INC., Defendant.	NO. 91-41-CIV-4-H
BURROUGHS WELLCOME CO., Plaintiff, v. NOVOPHARM, INC., Defendant.	NO. 92-134-CIV-4-H
BURROUGHS WELLCOME CO., Plaintiff, v. NOVOPHARM LTD., Defendant.	NO. 92-156-CIV-4-H

ORDER GRANTING JUDGMENT AS A MATTER
OF LAW IN FAVOR OF PLAINTIFF
BURROUGHS WELLCOME CO.
(Filed 7/22/93)

This matter is before the court on the plaintiff's motion for judgment as a matter of law filed June 30,

1993, and the plaintiff's renewed motion for judgment as a matter of law filed July 5, 1993. Also pending in this matter is the plaintiff's renewed motion for summary judgment filed June 18, 1993.

In the twenty-five months transpiring between the filing of the initial complaint in this consolidated patent infringement action on May 14, 1991, and the commencement of the trial on June 28, 1993, approximately five hundred forty-one pleadings have been filed and dozens of hearings on motions and discovery matters have been conducted by the court. The court has entered eighty-eight written orders and numerous bench rulings. Thus, the court is intimately familiar with the facts of this case and the legal contentions of the parties.

To state that the case has been hotly contested would be an understatement. The parties have amassed learned, experienced and sizable trial teams who have represented their clients zealously and competently.

The administrative complexity of conducting a trial of this magnitude has been enormous for the court and the parties. The sixty-year-old courtroom in New Bern, North Carolina, has been converted into a contemporary "high tech" facility utilizing "real time" court reporting and six computer-integrated video display monitors. It is highly conceivable that the cost of this trial for the parties exceeds $100,000 per day, in addition to the time and expense associated with this court and the jury. As this case enters its fourth week of trial, the parties estimate, somewhat conservatively the court suspects, that the trial will last an additional six to eight weeks.

With this preamble, the court will state briefly a synopsis of the procedural and factual background of the case. A more detailed statement of the procedural and factual background of the case can be found in the court's order dated June 3, 1993, denying plaintiff's motions for partial summary judgment.

PROCEDURAL BACKGROUND

Plaintiff Burroughs Wellcome Co. ("BW Co."), a research-oriented pharmaceutical company, owns and controls six United States patents covering various methods of using azidothymidine ("AZT") in the treatment of persons infected with the Human Immunodeficiency Virus ("HIV"). BW Co. manufactures and sells AZT under the brand name Retrovir. At issue in this case is the proper naming of inventors on the following six patents owned by BW Co.: 1) U.S. Patent No. 4,724,232, filed September 17, 1985, issued February 9, 1988; 2) U.S. Patent No. 4,828,838, filed October 21, 1987, issued May 9, 1989; 3) U.S. Patent No. 4,833,130, filed October 20, 1987, issued May 23, 1989; 4) U.S. Patent No. 4,837,208, filed October 20, 1987, issued June 6, 1989; 5) U.S. Patent No. 4,818,538, filed October 21, 1987, issued April 4, 1989; and 6) U.S. Patent No. 4,818,750, filed October 20, 1987, issued April 4, 1989. The court will refer to these patents collectively as "the BW Co. patents."

Defendants Barr and Novopharm Ltd. filed Abbreviated New Drug Applications ("ANDA") with the Food and Drug Administration ("FDA") on March 19, 1991, and June 26, 1992, respectively, seeking approval to manufacture and distribute a generic equivalent of Retrovir.

Both Barr and Novopharm Ltd. certified to the FDA, pursuant to 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e), that the BW Co. patents were either invalid or not infringed by the filing of their ANDAs. Barr asserted noninfringement for the reason, *inter alia*, that two scientists employed by the National Institutes of Health ("the NIH"). Dr. Samuel Broder and Dr. Hiroaka Mitsuya, were coinventors of the subject matter claimed in the six BW Co. patents but had not been named as inventors on the patents. Because Barr received a nonexclusive license from the NIH to exploit any patent rights the NIH, as the employer of Dr. Broder and Dr. Mitsuya, might have in the BW Co. patents, Barr alleged that its ANDA was not an act of infringement.

Similarly, Novopharm Ltd. asserted that Dr. Broder and Dr. Mitsuya were coinventors of the subject matter claimed in the BW Co. patents, but in support of its contention that the BW Co. patents were invalid. Novopharm Ltd. contended that BW Co. omitted Dr. Broder and Dr. Mitsuya from the BW Co. patents with the intent to deceive the patent office and thereby engaged in inequitable conduct before the patent office. Novopharm Ltd. asserted that this alleged inequitable conduct invalidated the BW Co. patents.

STATEMENT OF FACTS

The BW Co. patents name the following five scientists employed by BW Co. as inventors: Dr. Janet Rideout; Dr. David Barry; Dr. Sandra Lehrman; Ms. Martha St. Clair; and Dr. Phillip Furman (collectively referred to as "the BW Co. inventors"). BW Co. is a world leader in

antiviral therapy and experienced in retroviruses. BW Co. has been a leader in all aspects of the development of nucleoside analogs, particularly in their use as effective antiviral compounds.

The BW Co. inventors first began screening compounds for potential use as an AIDS therapy in 1984. In mid-1984, when the scientific community learned that AIDS was caused by a retrovirus, now referred to as HIV, the BW Co. inventors, specifically Ms. St. Clair, began screening compounds for antiretrovial activity against two murine retroviruses.[1]

On October 29, 1984, Dr. Rideout selected AZT, identified as BW Co. compound 509U81, for testing in the murine screens. Ms. St. Clair tested AZT in the murine screens and reported that AZT showed significant activity against FLV and HaSV at low concentrations. After obtaining these positive results, the BW Co. inventors met on December 5, 1984, to discuss patenting the use of AZT to treat patients infected with HIV. After subsequent meetings held in early January 1985, the BW Co. patent committee recommended that a patent application covering the use of AZT as an AIDS therapy be prepared for future filing.

On February 4, 1985, BW Co. sent a sample of AZT under the code name Compound S to Dr. Broder at the NIH for screening against HIV in human cells. In the letter accompanying the sample, Dr. Lehrman informed

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[1] The two murine retroviruses used by BW Co. for testing were the Friend leukemia virus ("FLV") and the Harvey sarcoma virus ("HaSV").

Dr. Broder that Compound S had been tested in murine and feline leukemia virus systems and that preliminary data was available showing that HIV replication had been inhibited at certain concentrations. Dr. Lehrman suggested that Dr. Broder screen Compound S at concentrations of 1, 5, 10, and 50 micromolars.

By February 6, 1985, a draft patent application for filing in the Untied Kingdom was prepared by BW Co. employees and its patent agents and attorneys. This draft application did not name the inventors, but it disclosed how to make various pharmaceutical formulations of AZT in an effective dosage range for the purpose of treating HIV infections in humans. The dosage ranges disclosed in the draft patent application encompassed the recommended dosage ranges approved by the FDA in 1987. Based upon the information contained in the draft patent application, three expert witnesses on behalf of BW Co.[2] and one expert witness designated by Barr[3] stated in depositions that the draft patent application teaches one of ordinary skill in the art how to use AZT to treat patients infected with HIV. The draft patent application was reduced to final form and filed in the United Kingdom on March 16, 1985.

Dr. Mitsuya tested Compound S against HIV in human cells in mid-February 1985. His tests demonstrated that Compound S was active against HIV. On February 20, 1985, Dr. Broder phoned Dr. Lehrman to report the results of Dr. Mitsuya's testing.

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[2] Dr. Katz, Dr. White, and Dr. Whitley.

[3] Dr. Levine.

DISCUSSION

Rule 50(a) of the Federal Rules of Civil Procedure provides that a court may grant judgment as a matter of law during a jury trial when, after a party has been fully heard on the issue, "there is no legally sufficient evidentiary basis for a reasonable jury" to find in favor of that party on that issue. In ruling on a Rule 50(a) motion, the court must consider all of the evidence in the light most favorable to the nonmoving party and determine "whether reasonable triers of fact could draw only one conclusion." *Bond v. Morton Buildings, Inc.*, 815 F. Supp. 944, 945 (S.D.W. Va. 1993). To avoid judgment as a matter of law, the nonmoving party must come forward with more than a scintilla of evidence to support the material aspects of his case. *Id.; see also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250-52 (1986).

Under Rule 56, summary judgment is proper where "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." The standard for summary judgment under Rule 56 is very similar to the standard for judgment as a matter of law under Rule 50(a).

Inventorship

The above facts are found by the court to be fully supported by the record. The parties and the court agree that the only real dispute in this case is the appropriate legal standard that will apply to these facts. The parties

candidly represent to the court that the resolution of the appropriate legal standard is outcome determinative.

In previous rulings, the court has defined conception as the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention as it is thereafter to be applied in practice. The court refused to adopt the legal standard asserted by the defendants in response to BW Co.'s motion for partial summary judgment that an inventor must have a "reasonable basis" for believing that an invention will work before conception can be complete.

The law of conception as understood by the court is comprised of two elements. The first element relates to the state of mind of the inventor – whether he had a definite and permanent idea of the complete and operative invention. This element is subjective; so long as the idea is sufficiently defined and preserved, the law does not require that the inventor's idea be reasonable, scientifically accurate, or capable of being proved. This legal definition of the first element of conception is the object of the parties' current dispute and permeates the whole of the defendants' case.

The second element asks whether the inventor's idea, as defined and preserved, enables one of ordinary skill in the art to reduce the invention to practice. This element is objective. The parties have no quarrel with the court's definition of the second element.

Defendant Barr has argued that the definition of conception requires that the BW Co. inventors must have a definite and permanent idea that AZT would be effective in treating humans suffering from AIDS. Barr contends

that it must be permitted to introduce evidence that challenges and undermines the murine screen used by the BW Co. inventors as a basis for their claimed definite and permanent idea that AZT would be effective in treating humans suffering from AIDS. Counsel for Barr has candidly stated that the heart of its case rests on the admissibility of evidence regarding the predictiveness, or lack thereof, of murine screens in forming the idea that AZT would be active against a human retrovirus.

In contrast, BW Co. contends that the phrase "definite and permanent" in the context of conception relates to the inventor's ability to describe and preserve his idea and *not* to the inventor's belief that the idea will actually work.

The court agrees with BW Co.'s contention regarding the definition of conception. The court does not believe that the phrase "definite and permanent idea" requires that the BW Co. inventors *know* that AZT would be effective in treating humans having AIDS. For conception to be complete, the law does not require an idea to be proven to actually work. The defendants candidly admitted that their case depends upon the evidence concerning the reliability or predictiveness of the murine screens used by the BW Co. inventors, which this court determines has no legal relevance.

In light of the candid representations of defendants' counsel that they would be unable to satisfy their burden of proof by clear and convincing evidence under the court's definition of the first element of conception, the court informed the defendants that it would consider BW Co.'s motions for judgment as a matter of law pursuant to

Fed. R. Civ. P. 50(a). With this notification, counsel for the defendants presented written offers of proof and were given additional time to further supplement their offers of proof. The court has very carefully reviewed the defendants' written offers of proof and supplemental offers of proof and afforded them an opportunity to be heard orally.

Having given the defendants the opportunity to be fully heard, the court will set forth its findings and conclusions in light of the legal definition of conception adopted by the court. Reviewing all of the evidence and resolving all inferences in favor of the defendants, the court finds no evidence which would enable the defendants to meet their burden of proof in this case. The pleadings in the case and the evidence presented in three weeks of trial testimony satisfy the court without doubt that no legally sufficient evidentiary basis exists for a reasonable jury to find that the BW Co. inventors did not have a complete conception of the invention independent of the testing performed by Dr. Broder and Dr. Mitsuya. The admissible evidence clearly establishes, and this court finds as a matter of law, that the BW Co. inventors formed a definite and permanent idea of using AZT as a therapy for AIDS without any inventive contribution from Dr. Broder and/or Dr. Mitsuya.

Furthermore, in light of all of the evidence, the court concludes that the BW Co. inventors' idea was sufficiently described to allow one of ordinary skill in the art to practice the invention. The evidence in the record shows that the draft patent application was sufficient to enable one of ordinary skill in the art to practice the invention, that is, to treat a patient infected with HIV

with an effective dosage amount of AZT. Thus, the evidence fully satisfies the second element of conception.

In reaching its legal conclusions on the elements of conception, the court has relied upon the holdings in such cases as *Hybritech, Inc. v. Monoclonal antibodies,* 802 F.2d 1367 (Fed. Cir. 1986), *Rey-Bellet v. Engelhart,* 493 F.2d 1380 (C.C.P.A. 1974), *MacMillan v. Moffett,* 432 F.2d 1270 (C.C.P.A. 1970), and *Applegate v. Scherer,* 332 F.2d 571 (C.C.P.A. 1964). The court notes further that a party who conducts tests wholly at the direction and instruction of another is merely a technician and not a conceiver and acts merely as a "pair of hands." The court finds that this last statement accurately characterizes the role played by Dr. Broder and Dr. Mitsuya. The evidence in the record shows that BW Co. sent Compound S to the NIH with specific instructions and directed the testing performed by Dr. Broder and Dr. Mitsuya.

Accordingly, the court concludes that BW Co. is entitled to judgment as a matter of law. The court finds that the evidence in this case is overwhelming and conclusive that the BW Co. inventors, and only the BW Co. inventors, first conceived of the idea of using AZT as a therapy for treating persons infected with HIV. Their definite and permanent idea was expressed in such documents as the February 6, 1985, draft patent application and the February 4, 1985, letter from Dr. Lehrman to Dr. Broder. In addition, the court has heard and considered the testimony of the inventors regarding their formation of the idea that AZT would be an effective AIDS therapy.

The court also finds that the evidence is equally strong in relation to U.S. Patent No. 4,818,750 claiming

the use of AZT to increase a patient's T-lymphocyte count. Novopharm Ltd. and Novopharm, Inc., contend that there is no evidence that the BW Co. inventors thought of this use until Dr. Broder and Dr. Yarchoan reported these results following the administration of AZT to a human during clinical trials. However, the court has heard substantial testimony that an increase in the T-lymphocyte count was an "obvious," natural phenomenon known to the BW Co. inventors that would result from the inhibition of a retrovirus.

Estoppel

Defendant Barr has also renewed its motion for partial summary judgment on the issue of estoppel, laches, and waiver. The court previously denied Barr's motion for partial summary judgment on these issues following oral argument on June 14, 1993. The court found that certain factual determinations precluded the entry of summary judgment.

Barr's primary contention in support of its motion is that the Property Clause of the United States Constitution holds that the government cannot be denied property rights through the assertion of the equitable doctrines of estoppel, laches, and waiver. Under the Property Clause and the cases applying it, government property may be disposed of only as authorized by Congress and government officials without proper authority cannot cause the government to lose its property rights. *See California v. United States*, 457 U.S. 273 (1982); *United States v. California*, 332 U.S. 19 (1947). Barr alleges that the government has never authorized the disposal of its patent rights

through estoppel, laches, or waiver, and, therefore, these equitable defense must be dismissed as a matter of law.

The court is not persuaded that the Property Clause is implicated in this action. Although a patent right is a property right, the rights being asserted by Barr in this case have not yet ripened into "property." The patent right being asserted[4] by Barr on behalf of the government in this action is the government's alleged ownership interest in the BW Co. patents.

Barr asserted in its previous motion for partial summary judgment on this issue that ownership rights in a patent inure *automatically* to the government. For the reasons stated below, the court disagrees with Barr's application and interpretation of this statement.

"At the heart of any ownership analysis lies the question of who first invented the subject matter at issue, *because the patent right initially vests in the inventor* who may then, barring any restrictions to the contrary, transfer that right to another, and so forth." *Beech Aircraft Corp. v. EDO Corp.*, 990 F.2d 1237, 1248 (Fed. Cir. 1993) (emphasis added). Only natural persons can be inventors.

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[4] The court questions whether the government is, in fact, asserting any rights or taking any action to protect its rights in this litigation. It is not a party to this proceeding, and it has repeatedly reminded the court that it is not a party to this proceeding. It participated very begrudgingly in discovery, which became the subject of numerous motions to compel culminating in an on-site inspection of the files of the NIH attended by this court. The only action taken by the government to preserve its alleged rights was the negotiation of a licensing agreement with the defendant Barr which obligated Barr to represent the government's interest in this action.

Id. at 1248 n.2. Because the government is not a natural person, the government cannot be an inventor. Therefore, patent rights cannot vest *automatically* in the government. The government must derive patent rights from an inventor.

In this case, the inventors from whom the government claims an ownership interest are Drs. Broder and Mitsuya. In order for the government to acquire an ownership interest in the BW Co. patents through Drs. Broder and Mitsuya, two conditions must be satisfied. First, Drs. Broder and Mitsuya must be inventors of the BW Co. patents. Second, Drs. Broder and Mitsuya must transfer, by assignment or otherwise, their ownership rights to the government.

Putting aside the first condition, the court finds that the government is not able to establish the second condition in order to support the contention that the government *has* an ownership interest to protect. Although a formal assignment is not necessary in order for the government to obtain ownership rights in the inventions of its employees, *see* Executive Order 10096; *In re Williams*, 228 U.S.P.Q. 381 (Comm'r Pat. 1985), federal regulations provide the proper procedures to be followed when a government employee seeks to establish patent rights. *See* 37 C.F.R. § 100.6(c)(3).

The record is devoid of any evidence showing that Dr. Broder and/or Dr. Mitsuya even filed or submitted an employee invention report identifying themselves as coinventors of the subject matter of the BW Co. patents. In fact, the court has found no evidence showing that Dr.

Broder and/or Dr. Mitsuya ever took *any* action to establish their status as coinventors. Therefore, the court finds no basis for finding that the government has a constitutionally-protected property interest in the BW Co. patents.

Accordingly, the court DENIES Barr's renewed motion for partial summary judgment on the issue of estoppel, laches, and waiver. Whether these equitable doctrines can be applied in this case is a question that cannot be decided as a matter of law. This ruling in no way expresses any opinion as to whether the elements of these doctrins [sic] can be satisfied in this case based upon the evidence.

CONCLUSION

For the foregoing reasons, the court hereby GRANTS BW Co.'s motion for judgment as a matter of law pursuant to Fed. R. Civ. P. 50(a)(1). The court finds that the BW Co. inventors had a complete conception, that is, they had a definite and permanent idea of a complete and operative invention as it was thereafter to be applied in practice, independent of any inventive contribution from Dr. Broder and Dr. Mitsuya. Having found that there is no basis in law for the contention that Dr. Broder and Dr. Mitsuya are coinventors, the court concludes that Novopharm, Inc., and Novopharm Ltd.'s defense of inequitable conduct fail as a matter of law and are hereby DISMISSED.

All other pending motions are hereby DISMISSED.

Pursuant to Fed. R. Civ. P. 50(a), judgment shall forthwith be entered in favor of the plaintiff Burroughs Wellcome Co.

This the 22nd day of July, 1993.

/s/ Malcolm J. Howard
MALCOLM J. HOWARD
United States District Judge

At New Bern, North Carolina
#19

United States Court of Appeals for the Federal Circuit

ORDER

Before MAYER, Circuit Judge, LOURIE, Circuit Judge, and SCHALL, Circuit Judge.

A petition for rehearing having been filed by the APPELLANT,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for rehearing be, and the same hereby is, DENIED.

The mandate will issue December 22, 1994.

FOR THE COURT,
FRANCIS X. GINDHART, CLERK

Dated: December 15, 1994

by /s/ Diane M. Frye
Diane M. Frye
Chief Deputy Clerk

cc: DAN K. WEBB, ROBERT F. GREEN
E. ANTHONY FIGG

BURROUGHS WELLCOME
V. BARR LAB, 93-1503
(DCT – 91-41-CIV-4)

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Note: Pursuant to Fed. Cir. R. 47.6, this order is not citable as precedent. It is a public record.

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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
NEW BERN DIVISION
NO. 91-41-CIV-4-H
NO. 92-134-CIV-4-H
NO. 92-156-CIV-4-H

BURROUGHS WELLCOME CO.,

Plaintiff,

v.

BARR LABORATORIES, INC.,

Defendant.

BURROUGHS WELLCOME CO.,

Plaintiff,

v.

NOVOPHARM, INC.,

Defendant.

BURROUGHS WELLCOME CO.,

Plaintiff,

v.

NOVOPHARM LTD.,

Defendant.

SECOND MODIFIED JOINT OFFER OF PROOF ON INVENTORSHIP, DECEPTIVE INTENT AND INFRINGEMENT ISSUES

(Filed July 22, 1993)

I. INTRODUCTION

Novopharm Ltd. and Novopharm, Inc. (collectively "Novopharm") have alleged that U.S. Patent Nos. 4,724,232; 4,828,838; 4,833,130; 4,837,208; 4,818,538; and 4,818,750 are invalid because (a) Burroughs Wellcome Co. ("BW") failed to join as inventors scientists from the National Institutes of Health

* * *

toxicology studies, Dr. Elion testified that the inability of the pharmacology studies to give any evidence of the antiretroviral activity of AZT has been admitted by BW.

d. Activities of Duke/FDA/Sloan-Kettering

79. Beginning in the Fall of 1984, BW sent numerous compounds which had shown activity in its mouse test (including Compound S) to Dr. Kent Weinhold at Duke University, Dr. Rosen Hardy at Memorial Sloan-Kettering Cancer Center and Dr. Gerald Quinnan at the FDA for further testing.

e. Duke

80. Dr. Weinhold and BW agreed that BW would not send all compounds which BW had tested in this screen for testing by Duke because of the complexity of Duke's test, the limited capacity of Duke's test and the time-consuming nature of Duke's tests.

81. BW agreed to send to Duke only those compounds which had tested positive in the BW screen, except for some negative controls. As such, the BW screen

was a screen to eliminate those compounds that did not test positive.

82. Duke initially performed two assays on compounds it received from BW for testing. One test was a direct reverse transcriptase assay fro measuring the activity of a compound against reverse transcriptase in a cell-free environment. The second test was a chronic infection assay for testing a compound for activity against HIV in chronically infected human cells.

83. On or about December 4, 1984, BW sent Compound S (AZT) to Dr. Weinhold for screening. On December 10, 1994 Dr. Weinhold reported to Dr. Lehrman that Compound S showed no activity in the direct RT assay. (TX4609; Weinhold Tr. 44, 48-49, 134-135; TX-2022; TX-4429).

84. On December 10, 1984, Dr. Weinhold reported to Dr. Lehrman the results of the chronic infection assay. (TX-2022; TX-4429) The results of the chronic infection assay showed a reduction in both reverse transcriptase activity and in cell viability. Those results meant that Compound S was *toxic* in the assay and that the assay did not show an antiviral effect on AZT. (Weinhold Tr. 143, 148).

85. As late as February 1, 1985, St. Clair reported that Compound S had shown no activity in the Duke chronically-infected cell assay. (TX-2021)

86. At some time, Dr. Weinhold began the development of a third test for determining the activity of a compound against HIV. In the third test, human cells newly infected with HIV were used. (Weinhold Tr. 150)

87. Activity of a compound in the newly-infected cell assay was determined by measuring reverse transcriptase activity. (Lehrman Vol. 1, Tr. 138-140).

88. Dr. Weinhold's early attempts at testing the activity of AZT in newly-infected cells were unsuccessful. Dr. Lehrman's notes of a December 28, 1984 telephone report from Dr. Weinhold reveal that Dr. Weinhold's newly-infected cell assay still needed work. (TX-2034; Lehrman Vol. 1, Tr. 129-130).

89. While Dr. Weinhold may have begun to experiment with his newly-infected cell assay in January to mid-February, 1985, (Weinhold Tr. 151; Lehrman Vol. 1, Tr. 140), it was not until March 19, 1985 that Dr. Weinhold first provided BW data showing the activity of Compound S against HIV in newly-infected cells. (TX-2035; Lehrman Vol. 1, Tr. 140). The timing Dr. Weinhold's positive results relative to Dr. Broder is consistent with Dr. Bolognesi's recollection that "it was always our impression that . . . Dr. Broder's laboratory was the first to achieve a positive result with Compound S". (Bolognesi Tr. 36).

90. The researchers at Duke understood that Dr. Broder's laboratory was the first to achieve a positive result with Compound S.

91. BW did not receive results indicating an antiviral effect for AZT from Dr. Weinhold's screen with the live AIDS virus and employing newly infected cells until after BW had received from Dr. Broder results indicating an anti-HTLV-III effect for Compound S.

92. Proffers 79-90 find support in, *inter alia*, the deposition testimony of Dr. Weinhold, Dr. Bolognesi, Dr. Furman, Dr. Lehrman, and Ms. St. Clair, and TX-4025, TX-4026, and TX-4027.

f. FDA

93. In late November, 1984, BW sent a number of compounds, including Compound S, to Dr. Quinnan, Division Director, Division of Virology in the Center for Biologies Evaluation and Research at the Food and Drug Administration (FDA) to run in Dr. Quinnan's assay.

94. Dr. Quinnan requested the compounds from BW and BW agreed to provide the compounds for the purpose of Dr. Quinnan's testing.

95. Dr. Quinnan tested the compounds for activity against the AIDS virus to determine whether the compounds had activity.

96. Dr. Quinnan conducted the tests on behalf of public health, not on behalf of BW.

97. Dr. Quinnan tested compounds on cultures of H9 (human) cells chronically infected with virus. Dr. Quinnan also tested compounds on cultures of H9 cells newly infected with virus.

98. From time to time during December 1984, January 1985 and February 1985, Dr. Quinnan reported to Dr. Lehrman of BW on the progress of his tests. (TX-4301; TX-2040; TX4309; TX4310; TX-2042; Quinnan Tr. 221)

99. BW did not receive results indicating an antiviral effect for AZT from Dr. Quinnan's screen with the

live AIDS virus employing newly infected cells until after BW had received from Dr. Broder results indicating an anti-HTLV-III effect for Compound S.

100. Dr. Lehrman's notes of telephone conversations with Dr. Quinnan reflect that at no time prior to February 20, 1985 when Dr. Broder reported the positive results he and Dr. Mitsuya had achieved with AZT, did Dr. Quinnan report to BW that Compound S was active against HIV in Dr. Quinnan's assays. (TX-4308; TX-2040; TX-4309; TX-4310; TX-2042; Quinnan Tr. 224-225, 229-234, 235-236, 238-239; Lehrman Vol. 2, Tr. 17).

101. Although Dr. Quinnan testified that he had obtained results "which indicated that the compounds probably inhibited replications of HIV" and that he had reported such results to BW, Dr. Quinnan further testified that his results were equivocal and that he did not have enough data to know whether the reduced viral replication he had observed was due to "toxic effects" or whether the compound was acting as a "true antiviral". (Quinnan Tr. 247 - 253)

102. Thus, Dr. Quinnan's assay was not able to distinguish activity of a compound tested from possible toxic effects of the compound.

103. The results obtained in Dr. Quinnan's assay for AZT, prior to March 1, 1985 did not distinguish between an anti-HIV effect and cytotoxity. (Quinnan Tr. 255-256)

104. Dr. Quinnan had described his methodology to BW sufficiently that BW was aware that his assay would not differentiate between a toxic effect and an antiviral effect.

105. Dr. Quinnan further testified that the information he had available based on the results of his tests, even knowing that the compound he was testing was AZT would not have allowed for a determination to be made whether or not it was to be effective against AIDS. (Quinnan Tr. 250-252; 259-262)

106. Even after Dr. Broder had reported his positive results to BW, Dr. Quinnan was "still vague" about the activities of Compound S and advised BW that repeat assays were in progress. (TX-2044; Lehrman Vol. 2, Tr. 35-39)

107. Even BW did not rely on Dr. Quinnan's test results. The people at BW who were interested in AZT, including possibly Dr. Lehrman, Dr. Barry and Dr. Furman, did not have confidence in Dr. Quinnan's results. It was a pervasive feeling at BW that Dr. Quinnan's result [sic] were not trustworthy or reliable. (Wise Tr. 97-99).

108. Proffers 92-106 find support in, *inter alia*, the deposition testimony of Dr. Quinnan, Dr. Wise, Dr. Lehrman, Dr. Furman, Ms. St. Clair, TX-4030, TX-4031, TX-4034, TX-4035, TX-4423, TX-4424, and TX-4425.

g. Sloan-Kettering

109. Dr. Hardy at Sloan-Kettering tested compounds submitted to him by BW for anti-retroviral activity in a screen using feline (cat) leukemia virus in cat cells. The feline leukemia virus differs from HIV. Hardy's test used cat cells chronically-infected with the feline leukemia virus. Hardy's test was not predictive of the activity of a compound against HIV.

110. A goal of the testing in cats was to find a treatment for feline leukemia virus in cats, as testified by Dr. Barry. (TX-4036, Deposition Testimony of Drs. Hardy, Furman, Ruprecht, Furmanski and Temin)

h. Toxicology/Pharmacology

111. Between 1981 and 1984, BW and its parent company, the Wellcome Foundation, extensively investigated AZT as an antibacterial drug and found no human use for AZT as a result of that investigation. BW, in 1984, did not consider that AZT would be a practical antibacterial agent for human use. Prior to November, 1984, AZT had no established use in humans.

112. BW investigated AZT as a veterinary drug.

* * *

144. Proffers 127-142 find support in, *inter alia*, the deposition testimony and expected trial testimony of Dr. Broder, Dr. Lehrman, and Dr. Bolognesi.

j. Drs. Broder and Mitsuya Discover Activity of AZT In Human Cells

145. On February 4, 1985, Lehrman sent Compound S to Dr. Broder and indicated that Compound S had demonstrated activity against mouse retroviruses.

146. At the time BW transmitted a sample of AZT for testing to Dr. Broder, BW's Lehrman told Dr. Broder that if Dr. Broder's results were encouraging, BW could expedite its progress into clinical trials. (TX-4401) The February 4 letter demonstrates that whatever preliminary

results might already have been obtained had not convinced BW that AZT was likely to be a treatment for AIDS. Lehrman keyed the future development of AZT to Broder and Mitsuya's results: "Hopefully, if you have encouraging results in a month or so we can expedite its progress into the clinic." (TX-416)

147. BW was waiting for the test results before it would or could begin clinical trials from Dr. Broder because BW did not know if Compound S would be active against HIV. Contrary to what the BW scientists now claim, if St. Clair's tests, along with those of Duke and the FDA were predictive and positive, BW would not have needed the results from Dr. Broder before it would start clinical trials.

148. Dr. Mitsuya tested Compound S with the ATH8 cell line in mid-February of 1985, and on February 20, 1985, Dr. Broder reported to Lehrman that Compound S was active against HIV in human cells, i.e., *in vitro*. (TX-4045)

149. Drs. Broder and Mitsuya discovered for the first time that AZT was active against HIV.

150. In February of 1985, the testing performed by Dr. Mitsuya required more than routine skill.

151. In February of 1985, the work performed by Dr. Mitsuya was not routine screening, but rather was original research requiring interpretation and intellectual contribution to obtain and analyze the results.

152. In 1984-1985, BW and the NIH were engaged in a collaboration based upon intellectual exchange for the purpose of developing a therapy for AIDS.

153. Dr. Broder confirmed by letter the telephone call in which he reported for the first time that Compound S was active against HIV in human cells. (TX-2053A)

154. Only after Dr. Broder advised BW of the positive test results for AZT did BW take action to move AZT forward as a treatment for AIDS. (TX-4044)

155. Marty St. Clair admitted that only after Dr. Broder reported the results of the activity of AZT against HIV did things start to happen and so fast that she kind of almost got lost behind. (TX-2009)

156. Within days after Dr. Broder's report of the discovery of activity of AZT against HIV, BW invited Dr. Broder to visit BW in North Carolina, and that visit occurred only a few days later, on March 1. (TX-4044, TX-4046)

157. On March 18, 1993, only a few weeks after receiving the positive results from Dr. Broder (TX-2055), Lehrman and Furman wrote the official proposal to establish a Project Group for AZT at BW. (TX-2294)

158. At the March 1, 1985 conference, BW scientists and Dr. Broder reviewed the NCI data concerning AZT and, with Dr. Broder's assistance, based upon his prior experience with suramin, started to plan clinical trails for AZT. (TX-4046)

159. Dr. Bolognesi, Dr. Weinhold and Dr. Quinnan did not attend the March 1 meeting and no meeting with them occurred to discuss their data for Compound S. (TX-4046)

160. Broder and BW continued to collaborate after Broder and Mitsuya determined the effect of AZT against the live AIDS virus. Broder and Mitsuya continued to test AZT in a battery of tests which were not directed by BW but the data for which was shared with BW. Broder collaborated with BW to develop the protocol for testing AZT in the clinic. Broder in fact supervised the first use of AZT. (Broder and Mitsuya Trial Testimony.)

161. BW itself considered Broder's contribution important and inventive. BW acknowledged on numerous occasions the central role played by Broder after his work had been completed and before this lawsuit was filed. BW stated in its internal newsletter, "Wellcome News," published in October 1985:

> In early 1985, *NCI* called Burroughs Wellcome with its findings: (AZT] was active against the human AIDS virus. In fact, *researchers at the NCI* said, it was the most active compound they'd looked at so far. The green light was on.

162. The BW internal publication, "The Retrovir Story by B.W. Co. People," stated:

> In February [1985], *Sam Broder* called Sandi Lehrman to report that [AZT] was positive against HIV. We knew we really had something then. Things really began to move incredibly fast.

163. Similarly at a press conference held on March 23, 1987, David Barry stated:

> In close collaboration with us, testing at the National Cancer Institute by Dr. Samuel Broder and his colleagues in late 1984 and early 1985

> showed that Retrovir did inhibit the multiplication of the human AIDS virus in the test tube.

164. A "chronological listing of the key activities" in AZT's development compiled by BW in 1985 indicates that within two weeks after receiving Dr. Broder's test results the decision was reached to move ahead and develop AZT as an antiviral.

165. The development of AZT at BW depended on the results of Dr. Broder's experiments with human cells infected with HIV.

166. During an interview conducted before this lawsuit, Dannie King, BW's AZT project leader, sated that BW reached the decision to move forward with AZT only after Drs. Broder and Mitsuya's work:

> [a]t the time the activity was identified – confirmed, let's say – against the AIDS virus, and that was in early 1985 that was confirmed by [Broder] – then the decision was taken by Cuatrecasas [to go forward with AZT].

(TX 2207 at 180564-65).

167. Sandi Lerhman of BW confirmed that AZT's development hinged upon the results of Broder's experiments with human cells infected with HIV: "With the demonstration by Dr. Broder that [AZT] is a potent inhibitor of HTLV-3 *in vitro*, plans for clinical evaluation of this drug are in progress." (TX 2295).

168. Proffers 144-166 find support in, *inter alia*, the deposition testimony and expert testimony of Dr. Broder, Dr. Mitsuya and Dr. Yarchoan, and the laboratory notebooks of Dr. Mitsuya.

k. Patent Activities

169. The Wellcome Foundation Patent Department routinely filed the first patent applications on BW's potential inventions and those applications routinely were filed first in the United Kingdom.

170. Mr. Garrett of the Wellcome Foundation Patent Department met appropriate BW personnel and with the BW patent committee to obtain information to draft the patent application for AZT.

171. Michael Jackson, the head of the Patent Department of The Wellcome Foundation, was responsible for deciding whether or not to file patent applications and when, not the BW patent committee. Nevertheless, before the NIH discovered the activity of AZT against HIV, the decision to file a patent application on

* * *

No. 94-1531

Supreme Court, U.S.
FILED
MAY 18 1995
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IN THE

Supreme Court of the United States

OCTOBER TERM 1994

NOVOPHARM, INC. and NOVOPHARM LTD.,

Petitioners,

—v.—

BURROUGHS WELLCOME CO.,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF IN OPPOSITION

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17pp

QUESTION PRESENTED

Whether the court below correctly held, based on its *de novo* review of the record, including several extensive offers of proof submitted by Petitioners, that Burroughs Wellcome Co. was entitled to judgment as a matter of law on its claim that United States Patent Nos. 4,724,232, 4,828,838, 4,833,130, 4,837,208 and 4,818,538 were valid and infringed by Petitioners.

IDENTIFICATION OF CORPORATE AFFILIATES PURSUANT TO RULE 29.1

Pursuant to Supreme Court Rule 29.1, Respondent Burroughs Wellcome Co. states that it is a North Carolina corporation and a wholly-owned subsidiary of The Wellcome Foundation Limited which in turn is a wholly-owned subsidiary of Wellcome, p.l.c. which was recently acquired by Glaxo, p.l.c. and which has changed its name to Glaxo Wellcome, p.l.c. All of the subsidiaries of Burroughs Wellcome Co. are wholly-owned.

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IN THE

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OCTOBER TERM, 1994

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NOVOPHARM, INC. and NOVOPHARM LTD.,

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Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

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BRIEF IN OPPOSITION

Respondent Burroughs Wellcome Co. ("BW Co.") respectfully submits that a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit should not issue because no question worthy of the exercise of the Court's certiorari jurisdiction is presented and because the decision below is in all respects correct.

COUNTER-STATEMENT OF THE CASE

The Petition contains numerous misstatements and omissions with respect to both the course of the proceedings before the District Court and the opinion and holding of the

Court of Appeals. Such misstatements and omissions necessitate this counter-statement. *See* Supreme Court Rule 15.1.

This case concerns the validity and infringement of six United States patents owned by BW Co. covering compositions and methods for using the drug zidovudine (more commonly known as "AZT") to treat persons infected with the Human Immunodeficiency Virus ("HIV").[1] A.021.[2] BW Co. manufactures and sells AZT under the brand name Retrovir®. A.548. BW Co. alleged that Petitioners Novopharm, Inc. and Novopharm Ltd. (collectively, "Novopharm") infringed the BW Co. AZT Patents under 35 U.S.C. § 271(e)(2) (1988) as a result of Novopharm Ltd.'s June 26, 1992 filing of an Abbreviated New Drug Application with the United States Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic copy of Retrovir®. A.023. Shortly after they were filed, the actions against Novopharm, Inc. and Novopharm Ltd. were consolidated for discovery and trial with an identical action then pending against Barr Laboratories, Inc. ("Barr"). A.022-23.

During discovery, and in the Pre-Trial Order, both Novopharm Ltd. and Barr admitted to infringing the BW Co. AZT Patents[3] and conceded that each of the five named BW Co. inventors was properly named. A.13056; A.551. As a result, the trial focused on the assertion by Novopharm that

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[1] The patents at issue on this petition are No. 4,724,232, No. 4,828,838, No. 4,833,130, No. 4,837,208 and No. 4,818,538 (collectively, the "BW Co. AZT Patents").

[2] References to "Pet. App. __" are to the Appendix to the Petition for a Writ of Certiorari. References to "Pet. __" are to the Petition for a Writ of Certiorari. References to "A. __" are to the Record on Appeal.

[3] Novopharm, Inc. did not admit to infringing the BW Co. AZT Patents; the judgment entered against Novopharm, Inc. was vacated as premature by the Federal Circuit due to insufficient support in the record on this issue. Pet. App. 8a n.6. BW Co. submits that this is sufficient grounds for denying the Petition on behalf of Novopharm, Inc. *Penfield Co.* v. *SEC*, 330 U.S. 585, 589 (1947).

the patents were invalid and/or unenforceable because certain scientists at the National Institutes of Health ("NIH") had not been named as co-inventors (A.550-51); it was claimed that the positive results obtained from their blind screening of AZT against HIV *in vitro*[4] contributed to the conception of the invention. Pet. App. 9a-10a. The crucial question, therefore, was whether the BW Co. inventors' conception was complete prior to any work of the NIH scientists relating to AZT. Pet. App. 9a. This complete conception was evidenced and corroborated by a fully enabling draft patent application that was prepared before the NIH scientists conducted their blind screening of AZT. Pet. App. 16a-17a.

In order to conform their theory to the facts, therefore, Novopharm and Barr were forced to construct a novel standard for determining when there has been a completed conception. Ignoring over 100 years of precedent on this issue, they argued that a conception of an invention is not complete unless and until the putative inventor has a "reasonable expectation" that the invention will work. Pet. App. 12a. Thus, both Novopharm and Barr sought to prove that various experiments with AZT performed by and on behalf of BW Co. (including those testing the effect of AZT against animal retroviruses) were not "predictive" of how AZT would actually work in humans and, therefore, could not form the basis for a "reasonable expectation" that AZT would be an effective therapy for humans infected with HIV; only the results of the blind screening of AZT against HIV obtained by the NIH scientists, they contended, provided such a "reasonable expectation". Pet. App. 9a, 36a-37a.

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[4] An *in vitro* study is an experiment conducted entirely in a laboratory system (*i.e.*, a test tube), as opposed to an *in vivo* study which is conducted in a living being. The term "blind screening" refers to the fact that when the NIH scientists screened AZT, it was identified only as "Compound S"--they admittedly did not know the name or structure of the compound they were screening. A.933-34; A.15106-116.

BW Co. pointed out that the standard urged by Novopharm and Barr was *not* the law and that, accordingly, the evidence on predictivity that they proffered was wholly irrelevant. Pet. App. 37a. Immediately following the opening statements, after attorneys for Novopharm and Barr had explained what they expected the evidence to show, BW Co. moved for judgment as a matter of law, arguing that such evidence was legally insufficient to prove that the NIH scientists had contributed to the conception of the inventions disclosed in the BW Co. AZT Patents (A.676); BW Co. renewed this motion following certain in-court admissions by Barr's counsel after the District Court sustained BW Co. objections to the relevance of certain questions posed by counsel. A.13294-98.

Finally, after the District Court sustained a BW Co. objection to Barr's use of a chart entitled "The Mouse Test Is Not Predictive Of Human Responses," Barr's counsel admitted, for the sixth time,[5] that defendants could not under *any circumstances* prevail at trial if they were not permitted to inquire into the "reasonableness" of the beliefs of the inventors as to whether AZT would be an effective therapy for people infected with HIV or to inquire into the "predictivity" or lack thereof of the positive results of the BW Co. tests of AZT against murine [mouse] retroviruses. A.3048-60. The Court then solicited from counsel for all parties their views on how the case should proceed. Both Barr and Novopharm urged the Court to reconsider its ruling on the legal test for conception. However, both Barr and Novopharm conceded that if the Court maintained its ruling, they did not have sufficient evidence to go forward. A.3070; A.3162-64. Barr's counsel advised the District Court:

> "[the parties] are in agreement on this point, that this is a legal question and that if you should rule in their favor, . . . I should not be going forward. But I don't have

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[5] A.453-54; A.775-76; A.2401-03; A.13024; A.13027.

> any--I mean, I don't have it. It's not here. And when I finished, you would be directing a verdict against me."

A.3070. Novopharm's counsel did not object or disagree with this statement.

At this point, the District Court, turning to the pending BW Co. motions for judgment as a matter of law, directed the parties to file offers of proof relating to *any* matter the parties wished the District Court to consider. A.3095; A.3119-21; A.3145-46; A.3150-53; A.3159-62; A.3171.

Novopharm's criticisms of this use of the Rule 50(a) procedure by the District Court and the Federal Circuit are unfounded. First, Novopharm complains that it was "forced to be 'fully heard'." Pet. 4-5. However, Novopharm was allowed to submit three separate offers of proof comprising more than fifty pages each and accompanied by hundreds of pages of documents. Significantly, in neither its appeal to the Federal Circuit nor its petition to this Court, has Novopharm pointed to a single fact or piece of evidence missing from its offers of proof that it would have presented to the jury had the trial proceeded.

Second, Novopharm complains that the Rule 50(a) procedure denied it the opportunity to present its case to the jury. Pet. 4. But as the language of the rule and the Advisory Committee Note to the 1991 amendment made clear, entry of judgment under Rule 50(a) is appropriate at any time prior to the submission of the case to the jury when it becomes apparent that a party is unable to carry a burden of proof that is essential to its case. The rule does not require that a party be heard by a jury. Indeed, the rule is designed to avoid the necessity of a jury trial when resolution can be accomplished as a matter of law based upon undisputed facts. Novopharm could point to no evidence that could sustain its heavy burden of proof, and judgment as a matter of law was appropriate.

Following receipt of the offers of proof and further argument from counsel, the District Court, having determined that the parties were fully heard, recessed to review the submissions and consider the motion. The next day the District Court issued a 16-page opinion granting judgment as a matter of law to BW Co. Pet. App. 29a-44a. The Court held that:

> "The law of conception . . . is comprised of two elements. The first element relates to the state of mind of the inventor--whether he had a definite and permanent idea of the complete and operative invention. This element is subjective; so long as the idea is sufficiently defined and preserved, the law does not require that the inventor's idea be reasonable, scientifically accurate, or capable of being proved.
>
> * * *
>
> "The second element asked whether the inventor's idea, as defined and preserved, enables one of ordinary skill in the art to reduce the invention to practice. This element is objective."

Pet. App. 36a. The Court further held that "evidence concerning the reliability or predictiveness of the murine screens used by the BW Co. inventors . . . has no legal relevance." Pet. App. 37a. Thus, the Court concluded that, "[r]eviewing all of the evidence and resolving all inferences in favor of defendants," there was "no evidence which would enable the defendants to meet their burden of [clear and convincing] proof in this case."[6] Pet. App. 38a.

Novopharm appealed the judgment of the District Court to the Court of Appeals for the Federal Circuit, challenging the District Court's interpretation of the law of conception and its

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[6] In addition, the District Court held that, because the work of the NIH scientists was done at the direction and instruction of BW Co., they had acted merely as a "pair of hands" and, therefore, *could not* have contributed to the conception of the invention. Pet. App. 39a.

conclusion that there was no admissible evidence which would support a judgment for Novopharm. After a *de novo* review of the record, the Federal Circuit unanimously affirmed the District Court's judgment with respect to five of the six BW Co. AZT Patents.[7] Pet. App. 1a-28a. In so doing, the Federal Circuit, contrary to Novopharm's assertion (Pet. 6), completely validated the District Court's interpretation of the law of conception—using the same language and citing the same cases to reach a virtually identical conclusion. *Compare* Pet. App. 11a-16a, 19a *with* Pet. App. 36a-37a, 39a.

Novopharm's petition for rehearing was denied by the Federal Circuit on December 15, 1994. Pet. App. 45a. Novopharm did not seek rehearing *en banc*.

REASONS FOR DENYING THE WRIT

THE FEDERAL CIRCUIT'S DISPOSITION OF THIS CASE PURSUANT TO LONG-ESTABLISHED PRECEDENT RAISES NO ISSUE WORTHY OF THIS COURT'S CONSIDERATION

This case is a paradigmatic example of the type of appeal that is unworthy of the exercise of this Court's certiorari jurisdiction--a fact that is evident merely from reading the questions presented identified by Petitioner.

Despite the fact that both the District Court and the Federal Circuit have extensively reviewed the factual record in this case and both have concluded that BW Co. is entitled to judgment as a matter of law on the issue of inventorship with

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[7] The Federal Circuit, by a 2-1 majority, vacated the judgment with respect to U.S. Patent No. 4,818,750. Pet. App. 23a. The retrial concerning this patent is scheduled for October, 1995. In addition, *in dicta*, the Federal Circuit rejected the District Court's determination that the NIH scientists had merely acted as a "pair of hands." Pet. App. 18a.

respect to five of the six BW Co. AZT Patents, Novopharm would have this Court conduct yet a third review of the record to determine whether there is sufficient admissible evidence to create a factual question on the inventorship issue. Pet. 12-13. In particular, Novopharm requests that this Court review "the totality of the evidence", including the results of experiments with AZT conducted by the BW Co. inventors and by scientists at other institutions, as well as dozens (if not hundreds) of pages of documents reflecting the contemporaneous activities of BW Co., in order that this Court may second-guess the conclusions reached by both of the courts below concerning this evidence. Pet. 9-13. The factual review that Novopharm seeks, however, plainly is not deserving of a writ of certiorari.

Recognizing this fact, Novopharm attempts to portray the decision of the Federal Circuit as a "depart[ure] from the accepted and usual course of judicial proceedings." Pet. 7-8. In so doing, Novopharm inexcusably misreads the opinion below as having "rejected the district court's interpretation of the law of conception" and, based on a single passage quoted out of context, claims that the Federal Circuit "recognized that scientific accuracy and reasonableness, and the ability of the idea to be proved, bear on conception." Pet. 6. Thus, Novopharm concludes that the Federal Circuit committed an error worthy of review on certiorari by failing to consider "facts in Novopharm's offer of proof which bore directly on the issue of conception: experimental failures of others to show the activity of AZT against HIV, prior to the NIH's success, and the effect of those failures on the BW scientists' states of mind." Pet. 7.

A plain reading of the Federal Circuit's opinion, however, reveals the fallacy in Novopharm's contentions. The Federal Circuit, as had the District Court, held that:

> the test for conception is whether the inventor had an idea that was definite and permanent enough that one

> skilled in the art could understand the invention; the inventor must prove his conception by corroborating evidence, preferably by showing a contemporaneous disclosure. An idea is definite and permanent when the inventor has a specific, settled idea, a particular solution to the problem at hand, not just a general research goal or research plan he hopes to pursue.

Pet. App. 11a (citation omitted); *see also* Pet. App. 37a-39a. Indeed, the Federal Circuit specifically rejected Novopharm's assertion that "scientific accuracy and reasonableness, and the ability of the idea to be proved, bear on conception" (Pet. 6):

> Novopharm suggest[s] that the inventor's definite and permanent idea must include a reasonable expectation that the invention will work for its intended purpose. . . . Without some experimental confirmation, they suggest, the inventor has only a hope or an expectation, and has not yet conceived the invention in sufficiently definite and permanent form. *But this is not the law*."

Pet. App. 12a (emphasis added).

Novopharm's interpretation of the Federal Circuit's opinion is based solely on a single passage from the opinion:

> A conception is not complete if the subsequent course of experimentation, especially experimental failures, reveals uncertainty that so undermines the specificity of the inventor's idea that it is not yet a definite and permanent reflection of the complete invention as it will be used in practice.

Pet. 6; Pet. App. 14a. To have any meaning, of course, the passage must be read in the context in which it appears--in this case, the context is a discussion of the inapplicability of simultaneous conception and reduction to practice cases. Pet. App. 13a-14a. In such cases, the invention is the result of trial and error research and the inventor cannot describe how to put the invention into practice until a successful experiment has

been performed. *Alpert* v. *Slatin*, 305 F.2d 891, 894 (C.C.P.A. 1962). The language upon which Novopharm relies does not, as Novopharm contends, mean that a specific and fully enabling conception of an invention ceases to be a conception when there is a subsequent experimental failure. The point of the language is that, in trial and error research, conception of a general goal is insufficient when the course of experimentation has not yet revealed to the inventor how the invention will be put into practice. In such a situation, the conception is not yet complete because the inventor is not in a position to make a disclosure of the invention that would enable its reduction to practice by one of ordinary skill. It is well established that,

> "conception has been achieved when 'the inventive idea is crystallized in all of its essential attributes and becomes so clearly defined in the mind of the inventor as to be capable of being converted to reality and reduced to practice by the inventor or by one skilled in the art.' *Technitrol, Inc.* v. *United States*, 440 F.2d 1362, 1369-70, 194 Ct. Cl. 596,609 (1971)."

Amax Fly Ash Corp. v. *United States*, 514 F.2d 1041, 1047 (Ct. Cl. 1975).

In this case, however, it was unnecessary to consider evidence of experimental failures by other scientists because evidence existed which completely corroborated the conception of the BW Co. inventors. Pet. App. 16a-17a. The Federal Circuit, as had the District Court, held that a February 6, 1985 draft British patent application "corroborates the claim that they had formulated a definite and permanent idea of the inventions by the time it was prepared." Pet. App. 16a; *see also* Pet. App. 38a-39a. Given this conclusion, Novopharm's assertion that the Federal Circuit should have considered evidence of purported experimental failures in determining inventorship is without merit and distorts the record.

Novopharm also attempts to create a certiorari-worthy dispute by mischaracterizing the Federal Circuit's opinion on the "pair of hands" issue as contrary to established law. Novopharm argues that "[o]nce the Federal Circuit held that the NIH scientists were more than a 'pair of hands,' it should have conferred joint inventor status to Drs. Broder and Mitsuya for contributing to the conception of the invention." Pet. 13. It further asserts that "[t]his is the first time that a contributor to an invention who has been found to be more than a mere pair of hands in reducing an invention to practice has not been afforded appropriate status as a coinventor. . . . It is simply not possible to be more than a pair of hands, i.e. to exercise inventive skill, without also being a joint inventor." Pet. 14.

Novopharm's argument is baseless. The assertion that one who, during the process of reducing an invention to practice, exercises skill greater than that of a pair of hands *ipso facto* makes an inventive contribution to the conception is without support in the caselaw. Indeed, the cases cited by Novopharm do not even suggest, let alone hold, that this equation is valid; these cases merely stand for the time-honored proposition that a conception is complete when one ordinarily skilled in the art can practice the invention without undue experimentation. *Sewall* v. *Walters*, 21 F.3d 411, 415 (Fed. Cir. 1994); *Land* v. *Dreyer*, 155 F.2d 383, 387 (C.C.P.A. 1946). Moreover, the question of whether the NIH scientists "exercised considerable skill" in the process of "simply confirming the operability of what the draft application disclosed" (Pet. App. 17a) is simply not relevant to determining whether the BW Co. conception was complete prior to that time. *Sewall*, *supra*, 21 F.3d at 415 n.3 ("the existence of research or experimentation does not necessarily indicate, by itself, that complete conception did not exist.") Indeed, as the Federal Circuit noted, "Novopharm concede[s] [that the draft patent application] would teach one skilled in the art to practice the inventions." Pet. App. 16a. Once a complete conception is

established, the question of whether the NIH scientists were a "pair of hands" is simply not material.[8]

CONCLUSION

The Petition for a Writ of Certiorari should be denied.

May 19, 1995

Respectfully submitted,

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[8] The inventions of the BW Co. AZT patents are directed to the treatment of patients, not the confirmation of activity in a test tube. Regardless of the skill required to perform the test tube procedure, it is undisputed that the BW Co. draft patent application contained sufficient detail to enable a skilled physician to treat a patient with AIDS or HIV disease. Therefore, the conception of the invention *as claimed* was complete before any NIH involvement.

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Nos. 94-1527 and 94-1531

In the Supreme Court of the United States

OCTOBER TERM, 1995

BARR LABORATORIES, PETITIONER

v.

BURROUGHS WELLCOME CO.

NOVOPHARM, INC., AND NOVOPHARM, LTD., PETITIONERS

v.

BURROUGHS WELLCOME CO.

ON PETITIONS FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTIONS PRESENTED

The question presented in No. 94-1527 is whether an inventor must have a reasonable expectation that an invention will work in order to conceive the invention for purposes of federal patent law.

The questions presented in No. 94-1531 are:

1. Whether the factual record before the district court precluded the court from entering judgment as a matter of law in favor of respondent under Rule 50(a) of the Federal Rules of Civil Procedure.

2. Whether, after an invention has been conceived by an inventor, someone who tests the invention with more than ordinary skill thereby becomes a joint inventor.

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In the Supreme Court of the United States

OCTOBER TERM, 1995

NO. 94-1527

BARR LABORATORIES, PETITIONER

v.

BURROUGHS WELLCOME CO.

NO. 94-1531

NOVOPHARM, INC., AND NOVOPHARM, LTD., PETITIONERS

v.

BURROUGHS WELLCOME CO.

ON PETITIONS FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

This brief is filed in response to this Court's order inviting the Solicitor General to express the views of the United States.

STATEMENT

Respondent Burroughs Wellcome Co. (Burroughs) holds patents for the use of a pharmaceutical compound called AZT (3'-azido-3'-deoxythymidine) to treat persons infected with the human immuno-deficiency virus (HIV), which causes a disease commonly known as acquired immune deficiency syndrome (AIDS). Burroughs brought suit against petitioner Barr Laboratories, Inc. (Barr) and

petitioners Novopharm, Inc., and Novopharm Ltd. (jointly Novopharm), alleging that those companies had infringed Burroughs' patents. The district court entered judgment for Burroughs (94-1527 Pet. App. 25a-37a), and the court of appeals largely affirmed the district court's decision (*id.* at 1a-23a).

1. In 1984, Burroughs commenced a research program to identify compounds that might be active against HIV, which was known to be a member of the Retroviridae or "retrovirus" family. See *Steadman's Medical Dictionary* 1720 (25th ed. 1990). Burroughs focused its research on a group of compounds known as nucleoside analogs. In October 1984, Burroughs began by screening the compounds against a class of murine (mouse) retroviruses that were thought to be analogous to HIV. Burroughs' testing revealed that administration of low concentrations of AZT produced significant activity against those retroviruses. 94-1527 Pet. App. 3a-4a.

At the time that it was carrying out the murine retrovirus screening program, Burroughs lacked the technical capability to test the compounds using the human retrovirus. However, the National Institutes of Health (NIH), which is a component of the Department of Health and Human Services (HHS), had that capability. Dr. Samuel Broder, a government scientist employed by the NIH, had developed a technique for testing potential AIDS drug treatments against clones of HIV-infected human cells. At Burroughs' request, Dr. Broder undertook to screen compounds supplied by Burroughs against his so-called ATH8 cell line. 94-1527 Pet. App. 4a.

On February 4, 1985, Burroughs supplied Dr. Broder with a sample of AZT, which Burroughs identified only as "Compound S." Two days later, before Dr. Broder had tested the compound, Burroughs prepared a draft British patent application for AZT. The draft patent application

described the use of AZT to treat patients infected with HIV, and it set out various formulations of AZT and associated dosages for administering the treatment. In mid-February 1985, shortly after Burroughs had prepared the draft patent application, one of Dr. Broder's colleagues tested "Compound S" on the ATH8 cell line. He found that the compound was extremely active against HIV. Dr. Broder informed Burroughs of the positive test results on February 20, 1985. 94-1527 Pet. App. 4a.

After receiving those positive results, Burroughs sought approval from the Food and Drug Administration (FDA) to market AZT as an AIDS treatment, and it initiated clinical trials. Burroughs filed British applications for AZT patents in March 1985, and it filed American applications for AZT patents in September 1985. In 1987, Burroughs received FDA approval to market AZT as an AIDS treatment drug. Burroughs eventually received six United States patents for the use of AZT to treat HIV-infected patients. 94-1527 Pet. App. 5a, 26a, 29a.

2. Under United States patent law, if two or more persons jointly make an invention, the patent application must name each of the joint inventors, and if a patent is issued, each inventor (or his assignee) is entitled to practice the invention. 35 U.S.C. 116, 262. See also 35 U.S.C. 256 (describing the procedure for adding omitted inventors and the consequences of a "deceptive" omission). In this case, Burroughs identified five of its own scientists as joint inventors in its AZT patent applications, but it did not name Dr. Broder or any other NIH scientist. See 94-1527 Pet. 7-8.

At the time that Burroughs filed the patent applications, and for a considerable period thereafter, the NIH scientists did not themselves assert a claim of inventorship. See 94-1527 Pet. App. 36a. In 1987, a congressional subcommittee held hearings that raised questions con-

cerning, among other things, the price that Burroughs charged for the AZT treatment. See *AIDS Issues (Part 1): Hearings Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 100th Cong., 1st Sess. 1-52 (1987). Thereafter, the NIH reexamined the role that its scientists had played in testing AZT for Burroughs. Based on that review, the NIH concluded that its scientists had been joint inventors of the patented inventions and should have been named in the Burroughs patent applications. See 94-1527 Pet. 8.

In July 1991, the NIH entered into an AZT licensing agreement with Barr, which manufactures generic drugs. C.A. App. A5368. The agreement stated that the NIH had "inchoate intellectual property rights" in the Burroughs AZT patents. *Id.* at A5386 (§§ 1.02, 2.01). The NIH granted Barr a nonexclusive license to market AZT in the United States for any use approved by the FDA. *Id.* at A5371, A5384, A5387 (§ 3.01, Apps. B & D). In return, Barr agreed to pay the NIH royalties equal to a percentage of Barr's net sales, as well as certain additional sums. *Id.* at A5372-A5373, A5385 (§§ 5.01-5.03 & App. C).

The licensing agreement required Barr to assume responsibility for legal actions "to establish an inventorship/ownership interest on the part of the Government" in the inventions covered by the Burroughs patents. C.A. App. A5388 (§ 15.01). The agreement permitted Barr to count 50% of its "reasonable legal expenses" as a credit against any future royalty obligations to the NIH. *Id.* at A5385, A5388 (§ 15.01 & App. C). However, the agreement did not obligate the federal government itself to participate in the litigation. *Id.* at A5388 (§ 15.01).

3. While the NIH and Barr were negotiating the licensing agreement, Barr took steps that precipitated this patent dispute with Burroughs. In March 1991, Barr applied to the FDA under 21 U.S.C. 355(j) (1988 & Supp. V

1993) for approval to manufacture and sell a generic version of AZT. In June 1992, Novopharm, a generic drug manufacturer that did not obtain a license from the NIH, filed a similar application. The filings of those FDA applications were themselves technical acts of patent infringement under 35 U.S.C. 271(e)(2). See *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 675 (1990).

Burroughs responded by suing Barr and Novopharm for patent infringement in federal district court. See 94-1527 Pet. App. 5a. Barr and Novopharm defended their actions on the ground that the NIH scientists were joint inventors and should have been named in the Burroughs patent applications. *Ibid.* Novopharm additionally contended that the omission of the NIH scientists was the result of "deceptive intent" on the part of Burroughs, rendering the patents invalid and unenforceable. *Id.* at 6a. See 35 U.S.C. 256. The dispute over joint inventorship entailed, among other things, a disagreement over when the inventions were made.

Burroughs contended that its scientists invented the patented uses of AZT no later than February 6, 1985, the date that Burroughs prepared its draft British patent application (see pp. 2-3, *supra*). In contrast, Barr and Novopharm contended that the inventive process was not complete until at least two weeks later, on February 20, 1985, after Dr. Broder and his NIH colleague screened "Compound S" against the ATH8 cell line and reported the favorable test results to Burroughs. If the inventions were made before the NIH scientists screened "Compound S," as Burroughs contended, then the NIH scientists by definition could not be joint inventors. Conversely, if the inventions were not made until after the NIH screening took place, then the role of the NIH scientists might qualify them for joint inventorship. See 94-1527 Pet. App. 7a.

The dispute over when the inventions were made rests on an underlying disagreement over the governing test for "invention" under federal patent law. See 35 U.S.C. 100(a). Generally speaking, the act of invention involves two components, conception and reduction to practice. See 35 U.S.C. 102(g). Conception is the inventor's mental formulation of a complete idea for the product or process. *Sewall* v. *Walters*, 21 F.3d 411, 415 (Fed. Cir. 1994); 3 D. Chisum, *Patents* § 10.04, at 10-48 (1994). Reduction to practice is the process of putting the idea into effect, either by building and testing the invention ("actual" reduction to practice) or by filing an enabling patent application ("constructive" reduction to practice). 3 D. Chisum, *supra*, §§ 10.05-10.06. See also 1 *Walker on Patents* §§ 3.11-3.12 (1984).

In this case, the dispute focused on the element of conception. Although the federal patent statutes refer to conception (see 35 U.S.C. 102(g)), Congress has left the task of defining conception to the courts. The courts have relied on the judicial definition set out in *Mergenthaler* v. *Scudder*, 11 App. D.C. 264 (D.C. Cir. 1897), which states as follows:

> The conception of the invention consists in the complete performance of the mental part of the inventive act. All that remains to be accomplished in order to perfect the act or instrument, belongs to the department of construction, not invention. It is therefore the formation, in the mind of the inventor, *of a definite and permanent idea of the complete and operative invention, as it is thereafter to be applied in practice*, that constitutes an available conception, within the meaning of the patent law.

11 App. D.C. at 276. See, *e.g.*, *Application of Tansel*, 253 F.2d 241, 243 (C.C.P.A. 1958) ("The *Mergenthaler* decision

has been repeatedly cited and approved by this court."); *Gunter* v. *Stream*, 573 F.2d 77, 80 (C.C.P.A. 1978) (following *Mergenthaler*); *Coleman* v. *Dines*, 754 F.2d 353, 359 (Fed. Cir. 1985) (same).

Under the *Mergenthaler* standard, conception is deemed complete when the inventor can describe the invention with sufficient clarity and precision to make an "enabling" disclosure—that is, "a disclosure which would enable a person of ordinary skill in the art" to practice the invention. *Tansel*, 253 F.2d at 243; see also *Coleman*, 754 F.2d at 359; 3 D. Chisum, *supra*, § 10.04[3], at 10-160. In this case, Burroughs contended that the draft British patent application was just such an enabling disclosure and that the preparation of the draft application on February 6, 1985, demonstrated that the Burroughs scientists had conceived the inventions by that date. 94-1527 Pet. App. 7a.

Barr and Novopharm evidently did not dispute that the draft patent application was enabling. See 94-1527 Pet. App. 13a, 29a. However, they contended that in "uncertain" or "experimental" fields, such as biology and pharmacology, conception is not complete until the inventor has a "reasonable expectation" that the invention will work. Under that proposed standard, even if a person has formed an otherwise definite and permanent idea of the invention and has made an enabling disclosure, he cannot be deemed to conceive the invention until he obtains experimental data or other information that would make it reasonable for him to expect the invention to work. In this case, Barr and Novopharm contended that the results of the murine retrovirus screening (see p. 2, *supra*) did not provide a reasonable expectation that AZT would be active against HIV in human cells and that the Burroughs scientists did not have a reasonable expectation until Dr.

Broder informed them of the results of the ATH8 cell line screening. See 95-1527 Pet. 9.

4. In June 1993, the district court commenced a jury trial of the parties' patent infringement and joint inventorship claims. During that trial, Barr and Novopharm sought to introduce evidence bearing on their "reasonable expectation" theory of conception. The district court disallowed the evidence on the ground that, as a matter of patent law, conception does not require the inventor to have a reasonable expectation that the invention will work. After allowing Barr and Novopharm to submit offers of proof on the reasonable expectation issue, the district court entered judgment for Burroughs as a matter of law pursuant to Rule 50(a) of the Federal Rules of Civil Procedure. See 94-1527 Pet. App. 25a-37a.

The Federal Circuit affirmed the judgment with respect to five of the six patents and remanded (for reasons that are not relevant here) with respect to the remaining patent. See 94-1527 Pet. App. 1a-19a. The court of appeals agreed with the district court that the legal test for conception does not include a "reasonable expectation" requirement. *Id.* at 9a-16a. The court held that, as long as the inventor "had an idea that was definite and permanent enough that one skilled in the art could understand the invention," his "belief that his invention will work or his reasons for choosing a particular approach are irrelevant to conception." *Id.* at 9a, 10a.

The Federal Circuit concluded that Burroughs' preparation of the enabling draft British patent application demonstrated that the Burroughs scientists "had formulated a definite and permanent idea of the inventions" before the NIH scientists confirmed that AZT was active against HIV. Hence, the NIH scientists could not be joint inventors. 94-1527 Pet. App. 13a-14a, 15a. The court agreed with Barr and Novopharm that the NIH scientists

had been more than "a pair of hands" in carrying out the ATH8 screening, but reasoned that the screening merely "confirmed the operability of the inventions" and was "part of the reduction to practice" rather than part of the conception. *Id.* at 14a-15a.

DISCUSSION

The legal questions presented in this patent case arise in a dispute involving AZT, which is currently the most widely used medicine for the treatment of AIDS. The outcome of this dispute may affect the price, and consequently the availability, of AZT to AIDS patients. The AIDS epidemic is one of this country's most pressing health problems, and the United States has a strong public health interest in facilitating the availability of AZT to AIDS patients at an affordable price. Nevertheless, the resolution of this case must ultimately turn on the proper construction of federal patent law, which embodies long-standing principles governing inventorship. Indeed, the incentives of the patent system, including the opportunities that system provides for the recoupment of expensive research costs, help to provide hope that more effective means than AZT for treating or preventing AIDS will be forthcoming.

1. The primary issue here is whether an inventor must have a reasonable expectation that an invention will work in order to conceive the invention within the meaning of patent law. In our view, the Federal Circuit's decision is correct. The court's rejection of the "reasonable expectation" standard rests on a sound interpretation of the controlling judicial precedents and does not conflict with any decision of this Court or any other court. The Federal Circuit's decision is also consistent with underlying principles of patent policy. Contrary to Barr's suggestions, it is not likely to impede the development of

future medical treatments for AIDS and other diseases. Accordingly, we do not believe that further review by this Court is warranted.

a. The Federal Circuit did not write its decision on a blank slate. This Court recognized the basic requirements of conception in *The Telephone Cases*, 126 U.S. 1 (1888), which upheld Alexander Graham Bell's right to a patent for the telephone. The Court ruled that Bell had established his conception of the invention when he applied for a patent, even though at that time "he had never actually transmitted telegraphically spoken words so that they could be distinctly heard and understood at the receiving end of his line." *Id.* at 535. The Court rejected the argument that "Bell had not in fact completed his discovery" (*ibid.*), explaining as follows:

> The law does not require that a discoverer or inventor, in order to get a patent for a process, must have succeeded in bringing his art to the highest degree of perfection. It is enough if he describes his method with sufficient clearness and precision to enable those skilled in the matter to understand what the process is, and if he points out some practical way of putting it into operation. This Bell did.

Id. at 536. The District of Columbia Circuit refined that principle in *Mergenthaler*, and for nearly a century, the Federal Circuit and its predecessor, the Court of Customs and Patent Appeals (CCPA), have followed the definition of conception set forth therein. See pp. 6-7, *supra*. That definition does not ask whether the inventor knows, or has reason to believe, that his invention works. Instead, it simply asks whether the inventor has developed "a definite and permanent idea of the complete and operative invention, as it is thereafter to be applied in practice." *Mergenthaler*, 11 App. D.C. at 276 (emphasis omitted).

Under the *Mergenthaler* standard, the test of conception is whether the inventor "is able to make a disclosure which would enable a person of ordinary skill in the art to practice the disclosure without extensive research or experimentation." *Applegate* v. *Scherer*, 332 F.2d 571, 572 (C.C.P.A. 1964). According to the Federal Circuit, Barr and Novopharm conceded that Burroughs' draft British patent application "would teach one skilled in the art to practice the inventions." 94-1527 Pet. App. 13a; see *id.* at 29a. Consequently, Burroughs had satisfied the prevailing test for conception by February 6, 1985, before the NIH scientists screened "Compound S" against the ATH8 cell line.

Contrary to Barr's suggestions (94-1527 Pet. 16-17), neither the Federal Circuit nor the CCPA has ever held that conception is incomplete until the inventor demonstrates a "reasonable expectation" that the invention will work. Indeed, the CCPA specifically rejected proposed tests of conception that would have looked to the inventor's knowledge, or lack of knowledge, about the efficacy of his invention. The CCPA's decision in *Applegate* is illustrative. In that case, a federal agency was conducting a screening program to find compounds that could control sea lampreys. A chemical company contacted the agency to suggest that one of its compounds might be effective. The company sent a sample to the agency, which tested it and found that it was effective. The company and the agency then filed rival patent applications, with each party claiming sole inventorship. See 332 F.2d at 571-572.

The agency argued that the company did not conceive the invention because, at the time that it sent the sample for testing, it did not know whether the compound would work. The CCPA squarely rejected that argument in terms similar to those used by this Court in *The Telephone Cases*, *supra*. The CCPA stated:

> [The agency] seem[s] to propose that there cannot *be* a conception of an invention of the type here involved in the absence of knowledge that the invention will *work*. Such knowledge, necessarily, can rest only on an actual reduction to practice. To adopt this proposition would mean, as a practical matter, that one could never communicate an invention thought up by him to another who is to try it out, for, when the tester succeeds, the one who does no more than exercise ordinary skill would be rewarded and the innovator would not be. Such cannot be the law. A contrary intent is implicit in the statutes and in a multitude of precedents.

332 F.2d at 573-574.

The CCPA's decision in *MacMillan* v. *Moffett*, 432 F.2d 1237 (C.C.P.A. 1970), makes the same point. In *MacMillan*, one company selected antiperspirant compounds for testing by another company. Moffett, a scientist employed by the first company, selected 69 compounds for screening, and the second company's scientists found that one of those compounds was highly effective. The CCPA held that Moffett was the sole inventor, even though he had "no knowledge that [the effective compound] would have new and unexpected properties over the prior art and over the other 68 compounds he selected." *Id.* at 1239. The court held that Moffett's "reasons or lack of reasons for including [the compound] are not relevant to the question of conception. The important thing is that he did think in definite terms of the method claimed." *Ibid.*; see 3 D. Chisum, *supra*, § 10.04[4], at 10-68 to 10-69.[1]

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[1] Strictly speaking, precedents such as *Applegate* and *MacMillan* hold only that an inventor does not need to *know* that his invention works. They do not hold that the inventor does not need a "reasonable expectation" that the invention works. Their reasoning, however, is at

In the lower court proceedings, Barr attempted to support its "reasonable expectation" test by reference to cases in which an invention was simultaneously conceived and reduced to practice. See *Smith* v. *Bousquet*, 111 F.2d 157 (C.C.P.A. 1940); *Alpert* v. *Slatin*, 305 F.2d 891, 894 (C.C.P.A. 1962); see generally 3 D. Chisum, *supra*, § 10.04[5]. According to Barr, those cases demonstrate that conception in speculative fields cannot occur until the inventor acquires a reasonable basis (through experimentation or otherwise) for believing that his invention will work. See 94-1527 Pet. App. 10a. The Federal Circuit carefully reviewed the "simultaneous conception and reduction to practice" cases and concluded that they do not involve an exception to the *Mergenthaler* test, nor do they require proof of "reasonable expectation" as an element of conception in speculative fields of research. See 94-1527 Pet. App. 10a-12a.

As the Federal Circuit explained, the CCPA's opinions in *Smith* and *Alpert* deal with an evidentiary problem under the *Mergenthaler* test—the difficulty of determining when an inventor who is proceeding by "trial and error" (*Alpert*, 305 F.2d at 894) has formed a definite and fixed idea of the ultimate invention. See 94-1527 Pet. App. 10a-11a. In that situation, "the reduction to practice can be the most definitive corroboration of conception, for where the idea is in constant flux, it is not definite and permanent." *Id.* at 11a. In this case, by contrast, the enabling draft British patent application supplied the necessary evidence that Burroughs had arrived at a "definite and permanent" idea of the patented methods of

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odds with a "reasonable expectation" test, for that test rests squarely on the premise that conception is complete as soon as the inventor "think[s] in definite terms of the method claimed." *MacMillan*, 432 F.2d at 1239.

using AZT to treat AIDS. Hence the evidentiary problem involved in cases such as *Smith* was not presented. *Id.* at 16a. See 3 D. Chisum, *supra*, § 10.04[5], at 10-75.[2]

Barr also relied below on a statement in *Biel* v. *Chessin*, 347 F.2d 898 (C.C.P.A. 1965), that when someone invents "a method of treating the human body" with a compound, conception requires "some * * * reasonable understanding or appreciation of the fact that the compound would work." *Id.* at 902-903. The Federal Circuit noted, however, that the quoted language in *Biel* was dictum that had not been treated as controlling in subsequent cases. 94-1527 Pet. App. 10a n.7. That court, which is the CCPA's successor, acted appropriately in declining to give force to that prior dictum. See *Metropolitan Stevedore Co.* v. *Rambo*, 115 S. Ct. 2144, 2149 (1995).

The Federal Circuit's reading of the "simultaneous conception and reduction to practice" cases is consistent with longstanding patent law principles, and its rejection of *Biel*'s never-applied dictum is sound. Prior to the Federal Circuit's ruling in this case, its case law may have created a legitimate question concerning the governing test for conception in "speculative fields," but the court has now dispelled whatever uncertainty existed among its own precedents and has obviated the need for further review. See *Wisniewski* v. *United States*, 353 U.S. 901, 902 (1957) (per curiam) ("It is primarily the task

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[2] The CCPA itself recognized that the concept of "simultaneous conception and reduction to practice" is "rarely applied." *Alpert*, 305 F.2d at 894. It confined that principle to priority disputes involving independent inventors, and it declined to invoke the principle in originality disputes involving collaborative research efforts. See *Applegate*, 332 F.2d at 573; *MacMillan*, 432 F.2d at 1240 ("*Applegate* * * * made it abundantly clear that such a doctrine does not apply in cases where the issue is originality or derivation."); 3 D. Chisum, *supra*, § 10.04[5], at 10-72.

of a Court of Appeals to reconcile its internal difficulties.").

b. The Federal Circuit correctly recognized that Barr's proposed "reasonable expectation" standard is not an established element of existing patent jurisprudence. Barr disagrees with that conclusion, but its principal arguments in this Court rest on policy considerations relating to "patent monopolies." See 94-1527 Pet. 13-14. Barr's policy arguments are not persuasive.

Barr argues that its "reasonable expectation" standard would increase the incidence of joint inventorship and thereby reduce the occurrence of "patent monopolization." See 94-1527 Pet. 16. Barr suggests that when a single inventor or firm holds a patent, it encourages an undesirable "patent monopoly" in which the patentholder is free to charge whatever the market will bear, without having to face competition from other firms selling the same invention. Barr theorizes that when two or more inventors hold a patent, greater competition and lower prices will result, because each inventor has an independent right under 35 U.S.C. 261-262 to market the invention. 94-1527 Pet. 16.

Barr's "patent monopolization" argument has several shortcomings. First, it is in significant tension with the fundamental policies of the patent laws. See U.S. Const., Art. I, § 8, Cl. 8 ("To promote the Progress of Science and useful Arts."). Congress has crafted a patent system that provides a right to exclude, which amounts to a limited legal monopoly as an incentive for the development of socially useful inventions. *Brenner* v. *Manson*, 383 U.S. 519, 534 (1966). Congress has determined the confines of that right, imposing prerequisites (such as utility, novelty, and non-obviousness, 35 U.S.C. 101-103) and restrictions (such as durational limitations, 35 U.S.C. 154). But Barr has pointed to nothing in the patent laws

expressing Congress's intent to promote joint inventorship as a means of limiting that right. At bottom, Barr's argument is an invitation to this Court to assume a legislative role. Barr asks this Court to modify the longstanding test for conception to alter the balance that Congress has struck to spur socially beneficial inventive efforts.[3]

Second, Barr's surmise that a "reasonable expectation" standard would encourage joint inventorship is open to serious question. Barr's argument assumes that a firm that does not yet have a "reasonable expectation" about its invention's efficacy will nonetheless turn the invention over to another firm for testing without first taking steps to protect itself against the potential loss of exclusive patent rights. That assumption is highly dubious. The first firm can generally ask the second firm to yield by contract whatever patent rights the second firm might otherwise acquire through the testing process. If the second firm is unwilling to conduct the testing under those terms, the first firm may be able to find someone else who is willing and able to perform the tests on the same terms. Alternatively, the first firm may be able to develop the necessary testing capabilities "in house," and presumably will do so if the potential economic payout from the invention makes it worthwhile.

Third, even when a "reasonable expectation" requirement would lead to jointly held patent rights in a particu-

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[3] The judicial resolution of patent disputes may affect the economic power of market participants, and courts may take into account the "basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly" when they decide patent law issues. *Brenner*, 383 U.S. at 534. But the courts evaluate that factor based on congressional intent and not merely on the basis of sentiments regarding the desirability of the durationally limited rights authorized by the patent law. See, *e.g.*, *id.* at 529, 532-535.

lar case, there is little reason to think that the result will be greater competition and lower prices for the patented invention. Joint inventors ordinarily will have a common interest in maximizing any profits made possible by the patent. As a result, joint inventors will have a strong mutual incentive not to engage in price competition.[4]

In addition to the patent "monopolization" argument, Barr suggests that the Federal Circuit's decision is unsound because it grants patent rights too freely, or at least prematurely, to companies that rely on unsupported speculation rather than research. Barr raises the specter that a firm can "become an inventor by claiming that any number of identified compounds will cure any number of identified diseases" (94-1527 Pet. 15), without believing (or having any basis for believing) that the compounds

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[4] In this case, a federal agency performed the testing at issue. Barr perhaps believes that its "reasonable expectation" standard would broaden the government's joint inventorship rights when it tests products and thereby reduce the prospect of monopoly pricing in those fields where the government conducts research. Such a belief, however, would be very speculative. It is true that government does not share the profit-maximization objectives of a private firm; indeed, federal agencies are prohibited from granting exclusive licenses that would substantially lessen competition or result in undue concentration of economic power. See 35 U.S.C. 209(c)(2). But to the extent that Barr's "reasonable expectation" test would tend to make the government a joint inventor, the government's unwillingness to take part in monopoly pricing would correspondingly increase the incentive for private firms to avoid the joint inventorship "problem" in the first place. The firm might do so either by using non-government testing resources or by entering into pre-testing contractual arrangements that limit the government's patent rights. See Federal Technology Transfer Act of 1986, 15 U.S.C. 3710a (1988 & Supp. V 1993) (authorizing federal laboratories to enter into "cooperative research and development agreements" with private companies and other "collaborating parties" that determine patent and licensing issues at the outset of government involvement); see also S. Rep. No. 283, 99th Cong., 2d Sess. 11 (1986).

actually cure the diseases. Barr implies that firms will be able to acquire new patent rights simply by drawing up lists of compounds and diseases. *Id.* at 18-19.

That scenario is not, in our view, a realistic one. First, even under the *Mergenthaler* standard, conception is not deemed to be complete until the invention has been embodied in an enabling disclosure. See 94-1527 Pet. App. 8a-9a, 13a; *Coleman*, 754 F.2d at 359 ("Conception must be proved by corroborating evidence which shows that the inventor disclosed to others his 'completed thought expressed in such clear terms as to enable those skilled in the art' to make the invention.") (quoting *Field* v. *Knowles*, 183 F.2d 593, 601 (C.C.P.A. 1950)). Second, merely conceiving an invention, without more, does not confer any patent rights whatsoever. The inventor must reduce the invention to practice, either actually or constructively (see p. 6, *supra*), and must do so promptly or risk losing whatever patent rights he might otherwise be entitled to. See 35 U.S.C. 102(g); accord *Alexander Milburn Co.* v. *Davis-Bournonville Co.*, 270 U.S. 390, 400 (1926). Even after conception and reduction to practice are complete, moreover, the inventor must be able to show that his invention satisfies the patent law's substantive requirements for patentability, such as novelty, utility, and non-obviousness. See 35 U.S.C. 101-103; accord *Brenner*, 383 U.S. at 528-536. The traditional test for conception employed by the Federal Circuit in this case does not eliminate those additional legal requirements for obtaining patents, and there is accordingly no reason for companies to respond to this decision, as Barr predicts (94-1527 Pet. Reply Br. 1-2), by spending their time fruitlessly drawing up arbitrary lists of compounds and diseases and putting them into draft patent applications.

On the other side of the coin, adoption of a "reasonable expectation" test would impose a potentially significant

burden on the patent process by complicating the task of proving conception. Under current law, the Patent and Trademark Office and the courts resolve conception disputes by requiring the inventor to present evidence that he had a definite and permanent idea comprising the invention. The inventor can be expected to create documentary evidence on that matter, such as Burroughs' draft patent application or an inventor's work diary, in the ordinary course of developing the invention. There is no reason to believe, however, that inventors routinely develop documentary evidence of their expectations concerning their inventions' effectiveness. As a result, if the approach urged by Barr were to be adopted, the parties and courts would be faced with the task of retrospectively constructing and evaluating a record of the inventor's subjective knowledge and beliefs. That task would encumber administrative proceedings and patent litigation with additional and, in our view, unnecessary uncertainty and expense.

In sum, we see no significant basis for believing that adoption of a "reasonable expectation" test would be desirable as a matter of patent policy. The test would be an administrative encumbrance but would not appear likely to change either the incentives for collaborative development of inventions or the allocation of patent rights among collaborators. There is no reason to believe that the substantial public interest in encouraging development of beneficial products, such as new medicines, would be furthered if the test were to become law.

2. Novopharm's petition (No. 94-1531) presents two additional objections to the decision below. Neither of them warrants review by this Court.

First, Novopharm argues that there was "sufficient evidence in the record" (94-1531 Pet. 8) to foreclose the district court from entering judgment as a matter of law

under Federal Rule of Civil Procedure Rule 50(a). Novopharm does not contest the legal standard for conception employed by the court of appeals, but argues only that "the totality of the evidence" (94-1531 Pet. 12) created an issue of fact for the jury to decide under that standard. *Id.* at 8. The question whether Novopharm's offer of proof (94-1531 Pet. App. 46a-58a) was sufficient to create a jury question under the Federal Circuit's legal standard is a factbound matter that does not warrant further review. See, *e.g.*, *United States* v. *Johnston*, 268 U.S. 220, 227 (1925) ("We do not grant a certiorari to review evidence and discuss specific facts.").

Second, Novopharm argues (94-1531 Pet. 13-14) that once the court of appeals determined that the NIH scientists acted as more than a mere "pair of hands" in screening "Compound S" (94-1531 Pet. App. 18a), the court should have deemed the NIH scientists to be joint inventors as a matter of law. That argument rests on a *non sequitur*. The degree of skill and expertise employed by the NIH scientists might have been relevant to the issue of joint inventorship if the Burroughs scientists had not already conceived the patented inventions when the NIH scientists performed their tests. But once it is recognized that under the findings in this case conception was complete by February 6, 1985, it follows that the skill employed by the NIH scientists thereafter is irrelevant.

CONCLUSION

For the foregoing reasons, the petitions for a writ of certiorari should be denied.

Respectfully submitted.

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No. 94-1531

In The

Supreme Court of the United States

October Term, 1995

NOVOPHARM, INC., and NOVOPHARM LTD.,

Petitioners,

v.

BURROUGHS WELLCOME CO.,

Respondent.

Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

REPLY TO BRIEF OF THE UNITED STATES AS AMICUS CURIAE

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REPLY TO BRIEF OF THE UNITED STATES AS AMICUS CURIAE

The Amicus Brief argues that "the question of whether Novopharm's offer of proof was sufficient to create a jury question under the Federal Circuit's legal standard is a factbound matter that does not warrant further review." (Amicus Br. 20). Amicus' contention is wide of the mark, for it ignores not only the guidelines established by this Court in *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 106 S.Ct. 2105 (1986), but also the fact that the very premise of the district court's Rule 50(a) judgment has been undermined by the Federal Circuit's decision in this case. The Federal Circuit also ignored key facts in Novopharm's offer of proof which must fairly be considered under the "controlling law."

There is no dispute that the Federal Circuit has now established new controlling law of conception for this case (Amicus Br. 14). The precedent established by the Federal Circuit departs markedly from the definition of conception on which the district court based its Rule 50(a) judgment.

The essential differences explained in the Federal Circuit's decision are:

(1) conception is more than a mere idea (16a);

(2) a person whose contribution to a collaborative effort is experimental may still be a joint inventor if his qualitative contribution contributes to the joint arrival at a definite and permanent idea of the invention as it will be used in practice (15a); and

(3) conception is not complete where subsequent experimentation "especially failures, reveals uncertainty that so undermines the specificity of the inventor's idea that it is not yet a definite and permanent reflection of the complete invention as it will be used in practice" (14a).

Here, the district court could not possibly have decided the case under the "controlling law" as required by Rule 50 because the Federal Circuit changed the controlling law at least insofar as the controlling law was expressed by the district court. The entire basis for the district court's Rule 50(a) judgment was thus fatally undermined.

The Federal Circuit then erred in failing to vacate the district court's judgment and remand the case for trial based on its clarification of the law. Instead, the Federal Circuit not only proceeded to decide the case on the merits, it exacerbated its error by ignoring critical facts in Novopharm's offer of proof, weighing evidence and ascribing credibility to witnesses, thereby improperly usurping the role of the jury. The Federal Circuit thus clearly failed to follow the guidelines of *Anderson* which mandates consideration of all evidence in the light most favorable to Novopharm and leaves credibility determinations, the weighing of evidence and the drawing of legitimate inferences to the jury.

The experimental uncertainty of whether AZT or any other drug could be effective against HIV, the negative experimental results from Duke and the FDA, the essential and unique experimental evaluation and contribution of Dr. Broder and Dr. Mitsuya, scientists who were

"uniquely qualified" to help the Burroughs Wellcome scientists, provide ample factual evidence upon which a jury could conclude that the BW scientists did not have a conception – a definite and permanent idea of the invention – of the use of an effective amount of AZT to treat HIV prior to the key contributions of Drs. Broder and Mitsuya under the controlling law enunciated by the Federal Circuit. Thus, Novopharm is asking this Court not to review facts in order to decide the inventorship question on the merits as Amicus contends, but to review the facts sufficiently to recognize the Federal Circuit's reversible error and to reverse and remand the case to the Federal Circuit.

The Amicus Brief dismisses Novopharm's "pair of hands" argument as a *non sequitur* because the skill employed by the NIH scientists after the adjudged conception date is irrelevant. Amicus' analysis is incongruous in that its reasoning overlooks the very definition of complete conception Amicus itself advocates, and Amicus fails to apply that definition to the Federal Circuit's holding.

Under the Federal Circuit's own precedent, as well as the controlling law announced in this case, as Amicus argues (Amicus Br. 11), a conception is complete only when one of ordinary skill in the art can reduce the invention to practice. Here, the conception of the invention simply could not have been complete on February 6, 1995 as Amicus contends, for the contributions of Drs. Broder and Mitsuya to the invention have been acknowledged to transcend the contribution of a skilled artisan.

Here, as the Federal Circuit found, Dr. Broder and Dr. Mitsuya were not a "mere pair of hands," i.e., they were not merely exercising ordinary skill. Dr. Broder and Dr. Mitsuya exercised "considerable skill" in conducting crucial experiments with their patented cell line (18a). Dr. Broder and Dr. Mitsuya worked independently (18a) of the Burroughs Wellcome scientists in performing their work and making the critical discovery of the effectiveness of AZT amongst other putative drugs that were also tried. Dr. Broder and Dr. Mitsuya were called on to interpret the results they obtained in their admittedly unique experimental system (18a). Dr. Broder and Dr. Mitsuya were "uniquely qualified" not only to perform essential experiments which demonstrated for the very first time the effectiveness of AZT against HIV in a human cell line, but to evaluate and to interpret those experimental results (18a). Dr. Broder and Dr. Mitsuya made critical experimental contributions which completed the conception of the claimed invention – the use of an effective amount of AZT for the therapeutic treatment of HIV.

It is simply not possible to be more than a mere pair of hands, as Dr. Broder and Dr. Mitsuya were in the conception of the use of an effective amount of AZT for the treatment of HIV, and not be a joint inventor. *Sewall v. Walters*, 21 F.3d 411, 415 (Fed. Cir. 1994); *Land v. Dreyer*, 55 F.2d 383, 387 (C.C.P.A. 1946). Indeed, neither the Amicus nor Burroughs Wellcome can point to a *single case* other than this one, where a party found to be more than a "pair of hands" has not been accorded inventorship status.

Novopharm respectfully requests that the Court issue a writ of certiorari to review the judgment of the Court of Appeals for the Federal Circuit.

Respectfully submitted,

Date December 26, 1995

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No. 94-1531

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1995

NOVOPHARM, INC. and NOVOPHARM LTD.,

Petitioners,

—v.—

BURROUGHS WELLCOME CO.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

RESPONDENT'S SUPPLEMENTAL BRIEF IN OPPOSITION

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RULE 29. 6 STATEMENT

Respondent Burroughs Wellcome Co. is now known as Glaxo Wellcome Inc., a North Carolina corporation. Glaxo Wellcome Inc. is wholly owned by Glaxo Wellcome Americas Inc., which is wholly owned by Glaxo Group Ltd., which is wholly owned by Glaxo Wellcome plc. All of the subsidiaries of Glaxo Wellcome Inc. are wholly owned. For ease of reference, respondent will continue to refer to itself as Burroughs Wellcome Co.

IN THE

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ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

RESPONDENT'S SUPPLEMENTAL BRIEF IN OPPOSITION

Respondent Burroughs Wellcome Co. ("BW Co.") respectfully submits this supplemental brief, pursuant to S. Ct. R. 15.8, in order to address the inaccuracies contained within Novopharm, Inc.'s and Novopharm Ltd.'s (collectively "Novopharm") Reply to Brief of the United States as Amicus Curiae.[1]

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[1] References to "Rep. U.S. Br. __" are to Petitioners' Reply to Brief of the United States as Amicus Curiae. References to "U.S. Br. __" are to the Brief for the United States as Amicus Curiae. References to "Opp. __" are to Respondent's Brief in Opposition. References to "Pet. __" and "Pet. App. __" are to the Petition for Writ of Certiorari and the Appendix thereto, respectively.

DISCUSSION

The Solicitor General, responding to this Court's order inviting him to express the views of the United States, heard interested parties, conducted its own legal and factual review and concluded that Novopharm's petition for certiorari is without merit. U.S. Br. 19-20. In reply, Novopharm simply reiterates its earlier arguments of error.

I. AMICUS CORRECTLY RECOGNIZED THAT THIS COURT SHOULD NOT RE-EXAMINE THE FEDERAL CIRCUIT'S DE NOVO REVIEW OF THE DISTRICT COURT'S DECISION

Novopharm asserts that since Amicus allegedly "admits" that the Federal Circuit established new "controlling law", the appeals court was required to reverse the District Court and remand the case for a new trial based on this "new" law. Rep. U.S. Br. 2. This position is meritless. First, the cited language merely points out that whatever uncertainty may have existed concerned only the applicability of the doctrine of simultaneous conception and reduction to practice and did *not* apply to the well-established law of conception relied upon by the trial court and the Federal Circuit. U.S. Br. 14 & n.2. Novopharm's claim that the Federal Circuit, *sub silentio*, eviscerated the legal test for conception relied upon by the District Court simply misreads that court's opinion. Opp. 7-10.

Second, even if the Solictor General's brief implies some pre-existing uncertainty about the law of conception in speculative fields, it does not follow that the District Court's Rule 50(a) judgment is wrong as a matter of law. The Federal Circuit completely validated the District Court's interpretation of the law of conception—using the same cases to reach a virtually identical conclusion. *Compare* Pet. App. 11a-16a, 19a *with* Pet. App. 36a-37a. Furthermore, as the Solictor General recognizes, Novopharm's purported test for complete conception has never been the law and the "Federal Circuit's

reading [of the relevant cases] . . . is consistent with long-standing patent law principles". U.S. Br. 14.

Third, assuming *arquendo*, that the Federal Circuit's opinion represents a change in the "controlling law"—which it clearly does not—there was no obligation to order a remand. By *de novo* affirmation of the District Court's decision, the Federal Circuit held that the District Court reached the correct conclusion anyway. Novopharm can point to nothing which would warrant this Court to consider this case or mandate a remand.

Recognizing that its change in "controlling law" argument is insufficient to justify its certiorari petition, Novopharm asks this Court to assess facts, review evidence and conclude that the Federal Circuit erred "by ignoring critical facts in Novopharm's offer of proof, weighing evidence and ascribing credibility to witnesses, thereby improperly usurping the role of the jury." Rep. U.S. Br. 2. Yet, it is precisely that request which the Solictor General properly found objectionable. U.S. Br. 20 (*citing United States* v. *Johnston*, 268 U.S. 220, 227 (1925) ("We do not grant a certiorari to review evidence and discuss specific facts.")). Contrary to Novopharm's weak denials, granting their petition would require this Court to engage in yet a third review of the factual record and, by so doing, act contrary to established practice. Opp. 7-9.[2]

II. AMICUS CORRECTLY CONCLUDED THAT WHETHER OR NOT BRODER AND MITSUYA WERE MERE "PAIRS OF HANDS" IS IRRELEVANT

Novopharm asserts that once the Federal Circuit concluded that Drs. Broder and Mitsuya were more than mere "pairs of

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[2] In the instant case, such a factual review is especially unwarranted given the Federal Circuit's refusal to re-hear the case, even after Novopharm directed its attention to those facts it felt may have been overlooked by the Federal Circuit.

hands", it could not have concluded that the conception by the BW Co. scientists was complete. Rep. U.S. Br. 3-4. Novopharm raised precisely this same argument below and the Federal Circuit rejected it. Though Novopharm may take offense, the Solictor General correctly described this argument as a *non sequitur*.

The premise that Drs. Broder and Mitsuya may have performed tests which may have required more than ordinary skill *after* the date upon which the Federal Circuit says a complete conception existed cannot logically lead to the conclusion that the BW Co. conception was incomplete. The false issue of whether Drs. Broder and Mitsuya exercised "considerable skill" in the process of "simply confirming the operability of what the draft application disclosed" (Pet. App. 17a) is legally irrelevant to the Federal Circuit's decision. Having conceded that the February 6, 1985 draft application was enabling (Pet. App. 16a), Novopharm cannot collaterally attack the Federal Circuit's ruling by relying on *post*-conception testing.

CONCLUSION

For the foregoing reasons, for the reasons set forth in Respondent's Brief in Opposition and for the reasons set forth in the Brief for the United States as Amicus Curiae, the petition for a writ of certiorari should be denied.

January 1996

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